§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

Jetstream Aircraft Limited (Formerly British Aerospace Commercial Aircraft Limited): Docket 95–NM–160–AD.

Applicability: BAe Model ATP airplanes having constructor's numbers 2002 through 2063 inclusive, certificated in any category.

Note 1: This AD applies to each airplane identified in the preceding applicability provision, regardless of whether it has been modified, altered, or repaired in the area subject to the requirements of this AD. For airplanes that have been modified, altered, or repaired so that the performance of the requirements of this AD is affected, the owner/operator must request approval for an alternative method of compliance in accordance with paragraph (c) of this AD. The request should include an assessment of the effect of the modification, alteration, or repair on the unsafe condition addressed by this AD; and, if the unsafe condition has not been eliminated, the request should include specific proposed actions to address it.

Compliance: Required as indicated, unless accomplished previously.

To prevent corrosion of the antenna mounting reinforcing plates and surrounding skin, which could result in reduced structural integrity of the fuselage pressure vessel, accomplish the following:

(a) Within 6 months after the effective date of this AD, perform a detailed external visual inspection to detect damage (i.e., corrosion, cracks, pillowing, and rivet pulling) of the antenna mounting reinforcing plates and surrounding fuselage skin in accordance with PART A of the Accomplishment Instructions of Jetstream Service Bulletin ATP–53–31, dated July 1, 1995.

(1) If no damage is detected, repeat the inspection thereafter at intervals not to exceed 1 year.

(2) If any damage is detected, replace the reinforcing plate with a new reinforcing plate and/or repair the surrounding fuselage skin at the applicable times specified in Figure 4 of the service bulletin, and in accordance with PART B of the Accomplishment Instructions of the service bulletin. Accomplishment of the replacement/repair constitutes terminating action for the repetitive inspection requirements of paragraph (a) of this AD.

(b) Accomplishment of the replacement/repair procedures specified in PART B of the Accomplishment Instructions of Jetstream Service Bulletin ATP–53–31, dated July 1, 1995, constitutes terminating action for the requirements of this AD.

(c) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, Standardization Branch, ANM–113, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Maintenance Inspector, who may add comments and then send it to the Manager, Standardization Branch, ANM–113.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the Standardization Branch, ANM–113.

(d) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

Issued in Renton, Washington, on March 4, 1996.

James V. Devany,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 96–5526 Filed 3–7–96; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 886

[Docket No. 93P–0277]

Ophthalmic Devices; Reclassification of Neodymium:Yttrium: Aluminum:Garnet (Nd:YAG) Laser for Peripheral Iridotomy

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule; notice of panel recommendation.

SUMMARY: The Food and Drug Administration (FDA) is proposing to reclassify the ophthalmic neodymium:yttrium:aluminum:garnet (Nd:YAG) laser (mode-locked or Q-switched) intended for peripheral iridotomy from class III (premarket approval) into class II (special controls). The agency is also issuing for public comment the recommendation of the Ophthalmic Devices Panel (the Panel) regarding the reclassification of this device. The Panel made this recommendation after reviewing the reclassification petition submitted by Intelligent Surgical Lasers, Inc. (ISL). FDA is also issuing for public comment its tentative findings on the Panel's recommendation and its intent to change the generic designation of the device from Nd:YAG laser for posterior capsulotomy to Nd:YAG laser for posterior capsulotomy and peripheral iridotomy. After considering any public comments on the Panel's recommendation and FDA's tentative findings, FDA will approve or deny the reclassification petition by order in the form of a letter to the petitioner. FDA's decision on the petition will be announced in the Federal Register. If the petition is approved and the device is reclassified into class II, FDA will publish a final rule to codify the reclassification.

DATES: Written comments by June 6, 1996.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Morris Waxler, Center for Devices and Radiological Health (HFZ–460), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20850, 301–594–2018.

SUPPLEMENTARY INFORMATION:

I. Introduction

On March 2, 1993, ISL submitted a petition under section 513(f)(2) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c(f)(2)), requesting that the ophthalmic Nd:YAG laser (mode-locked or Q-switched) intended for peripheral iridotomy be reclassified from class III into class II.

The subject device is automatically classified into class III under section 513(f)(1) of the act because it is not within a type of device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, it is not substantially equivalent to such a device, and it is not substantially equivalent to a device placed in commercial distribution since May 28, 1976, which was subsequently reclassified into class II or class I.

Section 513(f)(2) of the act provides that FDA may initiate the reclassification of a device classified into class III under section 513(f)(1) of the act, or the manufacturer or importer of the device may petition the agency to reclassify the device into class I or class II. FDA's regulations in 21 CFR 860.134 set forth the procedures for filing and review of a petition to reclassify these class III devices. In order to reclassify the ophthalmic Nd:YAG laser (mode-locked or Q-switched) for peripheral iridotomy into class II, it is necessary that the proposed new class has sufficient regulatory controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use.

II. Background

Nd:YAG lasers originally were developed for industrial applications, and were successfully employed in such industries as watchmaking prior to the initiation of clinical trials in Europe and the United States. Therefore, the basic principles of operation of the device

were scientifically established well before any clinical testing of the device in ophthalmic surgery.

Surgical iridectomies, i.e., manual surgical excisions of part of the iris, were performed, with mixed results, in the late 1800's to relieve the symptoms of glaucoma. In 1920, the differences between the various types of glaucoma were described and it then became apparent why the surgery relieved the symptoms of some patients and not others. As a result, peripheral surgical iridectomies were then performed only on patients with pupillary-block (angle-closure) glaucoma.

Argon laser iridotomies, surgery with an argon laser to create an iris hole, became the preferred treatment for most cases of angle-closure glaucoma in the 1970's. Although there were advantages to the use of argon lasers (reduced risk of flat chamber, wound leak, endophthalmitis, malignant glaucoma, and lens subluxation), there were different complications associated with the new modality (permanent corneal burns, retinal burns, iritis, localized cataract formation, posterior synechiae, failed patency, intraocular pressure (IOP) rises and iris pigmentation).

The next treatment modality, iridotomy with the Q-switched Nd:YAG laser, was introduced during the early 1980's to treat angle-closure by a mechanical cutting effect to create peripheral iridotomies rather than the thermal effect of argon lasers. Because the technology permitted tissue disruption through a transparent medium with negligible heat generation, the Nd:YAG laser appeared to be ideal for ophthalmic surgery on opacified posterior capsular membranes, thus avoiding the risks involved in traditional invasive surgery as well as the thermal effects characteristic of other ophthalmic laser devices. Clinical trials were conducted and, subsequently, FDA granted premarket approval for three CooperVision Nd:YAG lasers (models 2000 and 2500 in 1985; model 2300 in 1986) for discission of the posterior capsule of the eye (posterior capsulotomy).

On January 24, 1986, the Medical Laser Manufacturers Association (MLMA) submitted to FDA, under section 513(e) of the act and 21 CFR 860.120, a petition for a change in the classification of the ophthalmic Nd:YAG laser (mode-locked or Q-switched) intended for posterior capsulotomy. On February 20, 1986, the MLMA amended its petition to include section 513(f)(2) of the act and 21 CFR 860.134 of the regulations as a basis for its requested relief. The petition requested that the ophthalmic Nd:YAG laser (mode-locked or Q-switched), intended for posterior capsulotomy, be reclassified from class III into class II. FDA referred the petition to the Panel for its recommendation as to whether the device should be reclassified. On May 22, 1986, during an open public meeting the Panel recommended that FDA reclassify the device from class III into class II when intended for use in posterior capsulotomy. The Panel identified the following devices as examples of the generic type of device: The Meditec OPL-3, the M-Tec 2000, the Horizon 2000, the Horizon 2500, and the YAG-100.

The Panel also recommended that this generic type of device be identified as the ''Nd:YAG laser for posterior capsulotomy.'' On December 14, 1987 (52 FR 47454), FDA published in the Federal Register a notice announcing the Panel's recommendation. On March 31, 1988, FDA ordered (by letter to MLMA) the reclassification of the Nd:YAG laser intended for posterior capsulotomy and substantially equivalent devices of this generic type from class III into class II.

On March 2, 1993, ISL submitted to FDA, under section 513(f) of the act, a petition requesting reclassification of the ophthalmic Nd:YAG laser (mode-locked or Q-switched) intended for peripheral iridotomy from class III into class II (Ref. 1). The agency referred the petition to the Panel for its recommendation on the requested change in classification.

III. Recommendation of the Panel

The Panel met on October 28, 1993, in an open public meeting to discuss the subject device. After considering the published studies, published data on laser parameters for safe and effective Nd:YAG iridotomy, and the guidelines for laser iridotomy published by the American Academy of Ophthalmology (Ref. 2), the Panel recommended that the ophthalmic Nd:YAG laser (mode-locked or Q-switched) intended for peripheral iridotomy be reclassified from class III into class II. The Panel believed the petitioners had presented sufficient data to demonstrate that special controls can be established to provide reasonable assurance of the safety and effectiveness of the device for its intended use. The Panel also noted that the procedure is well understood and widely used by most ophthalmologists in the United States, as evidenced by the discussion of the Panel members (Ref. 3 p. 83).

IV. Device Description

The ophthalmic Nd:YAG laser intended for peripheral iridotomy consists of a mode-locked or Q-switched solid state Nd:YAG laser that generates short pulse, low energy, high power, coherent optical radiation. When the laser output is combined with focusing optics, the high irradiance at the target site causes tissue disruption via optical breakdown. A visible aiming system is utilized to target the invisible Nd:YAG laser radiation on or in close proximity to the target tissue.

A. Principles of Operation

The Nd:YAG laser is one component of a device system that also includes conditioning optics, a delivery system, an aiming system, and operator controls. Its laser beam must be shaped by conditioning optics to a configuration with a specific profile and desired characteristics. The physical properties of the Nd:YAG laser beam that directly influence the ability of the device to perform its intended function safely and effectively are its invisible infrared beam at a wavelength of 1,064 nanometers, output pulse generating method, output energy, pulse width, spatial mode, convergence angle, spotsize, and pulse repetition frequency. The only variable that is selected by the ophthalmic surgeon during the iridotomy procedure is the device's output energy.

While other types of lasers (e.g., the argon laser) used for ophthalmic surgery employ long duration exposures to achieve thermal tissue effects for photocoagulation, tissue cutting, or tissue destruction, the ophthalmic Nd:YAG laser (mode-locked or Q-switched) intended for peripheral iridotomy uses very short duration exposures (pulses) that are focused precisely to small spot sizes and that produce a high local irradiance (power density). The combination of short exposure duration and high irradiance results in nonlinear absorption of the radiation by the target tissue, causing tissue disruption through optical breakdown. The plasma generated by the process of optical breakdown provides protection for posterior tissue in direct line with the incident beam. These unique characteristics permit the ophthalmic Nd:YAG laser to perform a patent iridotomy with reduced inflammation, regardless of iris pigmentation.

B. Device Specifications

Mode-locked laser output consists of a train of 7 to 10 pulses with a pulse duration of about 30 nanoseconds and a pulsewidth of about 30 picoseconds. Q-switched laser output consists of single pulses, with pulsewidths of about 2 to 20 nanoseconds in duration.

The typical threshold of optical breakdown of tissue in air for mode-locked lasers is 10^{14} watts per centimeter squared, and for Q-switched lasers is 10^{11} watts per centimeter squared. The threshold for optical breakdown of tissue in an aqueous environment appears to be lower but varies depending upon the nature of the tissue. For disruption of the iris of the eye, an energy setting of 4.0 to 6.0 millijoules results in optical breakdown creating the desired tissue effect after application of 1 to 4 bursts that contain 1 to 4 pulses/burst (Refs. 10, 11, 12, 13, 14, and 15).

In addition to the laser, the other two main components of the system subject to the petition are a visible light beam aiming system and a slit-lamp biomicroscope used by the operator to target the treatment laser beam and to visually monitor the treatment process.

V. Summary of Reasons for the Recommendation

The Panel based its recommendation on the data and information contained in the petition and presented during the open committee discussion during the Panel meeting on October 28, 1993. After review and consideration of the available information, the Panel gave the following reasons in support of its recommendation to reclassify the generic type ophthalmic Nd:YAG laser (mode-locked or Q-switched) intended for peripheral iridotomy from class III into class II:

(1) The device is not an implant.

(2) General controls by themselves are insufficient to provide reasonable assurance of the safety and effectiveness of the device.

(3) There is sufficient publicly available information to establish special controls to assure the performance of the device for its intended use. Also, there is sufficient publicly available information to demonstrate that the risks to health have been determined, and that the relationship between the device's performance parameters and risks and its safety and effectiveness have been established by valid scientific evidence.

(4) Various safety features of medical lasers are already controlled by existing FDA standards (21 CFR 1040.10 and 1040.11) promulgated under the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b).

The Panel believed that the following devices identified in the petition are representative of the generic type of device: the NIDEK YAG-100; the NIDEK 200; the Coherent 9900; and the Meridian LASAG MR-2.

VI. Risks To Health

Based on publicly available information establishing that it can successfully perform a discission of the iris (iridotomy), the Panel concluded that the ophthalmic Nd:YAG laser (mode-locked or Q-switched) intended for peripheral iridotomy is effective for its intended use. The Panel also determined that the foreseeable risks to health associated with the device are related to either unintentional damage to nontarget tissue or postoperative complications resulting from user error or device malfunction. These risks include corneal damage or edema, iritis, corectopia, lenticular opacities, retinal damage, transient elevation of IOP, failure to obtain iridotomy, precipitation of angle-closure attack, late closure of iridotomy, and iris atrophy. The risks of these adverse effects have been documented to be low and acceptable when the device is used in accordance with its directions and appropriate postoperative care is followed.

The use of the Nd:YAG laser for peripheral iridotomy may be contraindicated for patients without a clear cornea or aqueous, patients with chronic uveitis, patients with a tendency to bleed, patients on anticoagulant therapy, and patients with a glass intraocular lens.

VII. Summary of Data Upon Which the Recommendation is Based

During its review and discussion of the petition, the Panel paid close attention to the risks associated with the use of the device. The clinical studies included in the petition reported few risks to health, and the few that were reported were clearly identified. The Panel concluded that special controls can be established to provide reasonable assurance of the safety and effectiveness of the device when intended for peripheral iridotomy. The incidence rates of iridotomy closure, vision loss due to progression of laser induced lens or corneal damage, additional filtration surgery, transient iris bleeding, transient IOP spike, focal lens opacities, nonprogressive corneal endothelial changes, retinal damage, focal corneal opacities, mild iritis, and hyphema associated with Nd:YAG laser iridotomy are either lower than those for argon laser surgery or conventional surgical iridotomy or are self-limiting and not persistent.

Del Priore, et al. (Ref. 4) compared iridotomies using the Nd:YAG laser and argon laser in a prospective, randomized clinical study. The study focused on 43 patients (86 eyes) followed for 20 months (mean followup time 27 ±7 months). The mean preoperative visual acuity in the argon treated and the Nd:YAG treated eyes was 6/12 ±3 Snellen lines and did not change postoperatively. No retinal detachments or laser burns of the macula were detected. Iridotomy closure was not observed in any of the Nd:YAG laser treated eyes, but 9 (21 percent) argon iridotomies required retreatment. Visual loss due to progression of laser induced lens or corneal damage was not observed in any eye. Nine of 43 (21 percent) argon laser treated eyes and 8 of 43 (19 percent) Nd:YAG laser treated eyes required laser trabeculoplasty for further intraocular pressure lowering after iridotomy. Transient iris bleeding was encountered in 19 (44 percent) Nd:YAG laser treated eyes, but was not seen in any argon treated eyes. Six (32 percent) of the eyes with transient bleeding had IOP elevations greater than 10 millimeters (mm) Hg within the first 3 hours, and the IOP spike was greater than 20 mm Hg in four (17 percent) of these eyes. Focal opacification of the anterior lens capsule was seen in 23 (53 percent) argon laser treated eyes and none of the Nd:YAG laser treated eyes. This difference is statistically significant ($P<0.01$). Focal corneal endothelial opacities were encountered in 13 (30 percent) Nd:YAG laser treated and 11 (26 percent) argon laser treated eyes. Neither type of opacity enlarged clinically, and both tended to regress. Clinically significant corneal edema or corneal decompensation did not develop in the eyes of either treatment group during long term followup. Although several different Nd:YAG lasers (AM YAG-100 (American Medical Optics), Coherent JK Nd:YAG, and Coherent 9900) were used in the study, no differences were indicated by the results. The Nd:YAG laser offers intraoperative advantages in patients who cannot maintain a steady head position and fixation, and is independent of iris color. The Nd:YAG laser is also regarded as the treatment of choice in most patients with chronic pupillary-block glaucoma (Ref. 4).

In other studies, Fleck, et al. (Ref. 5) compared Nd:YAG laser iridotomy with and without argon laser pretreatment and concluded that argon laser pretreatment offers no advantage over primary Nd:YAG laser iridotomy. On the other hand, Goins, et al. (Ref. 6) found that argon laser pretreatment significantly reduced the incidence of hemorrhage during Nd:YAG iridotomy ($p=0.012$). Robin and Pollack (Ref. 7) found that hyphema is not clinically significant when eyes are pretreated with the argon laser. Of the Nd:YAG

iridotomies they studied, 67 percent (8/12) had operative hemorrhages, while 17 percent (2/12) of the argon pretreated eyes had hemorrhages. Robin and Pollack (Ref. 7) also reported a lower incidence of bleeding when eyes were pretreated with the argon laser. McGalliard and Wishart (Ref. 8) studied 81 eyes with shallow anterior chambers and raised IOP. Iridotomies were performed to prevent further angle closure glaucoma (ACG) and to remove pupillary block that could have contributed to the raised IOP. In eyes where there was no peripheral anterior synechia (PAS) there was no drop in IOP, but in eyes with well established PAS 69 percent showed a drop in IOP. Jiang (Ref. 9) also found a very significant difference between the preoperative values and the postoperative values at 3-year followup. In a study of 31 patients (40 eyes with persistent angle closure glaucoma (PACG)), the iridotomy controlled the IOP, and the iridotomy hole closed spontaneously in four eyes. The success rates were 94 percent at 6 months, 91 percent at 2 years, and dropped to 82.4 percent at the end of the third year. Romano, et al. (Ref. 10) compared Nd:YAG iridotomy with conventional surgical iridectomy. They found that in the nonlaser-treated group, pilocarpine alone controlled the IOP. In the laser treated group, eyes without PAS required fewer medications to maintain normal pressures than eyes with PAS required.

Regarding Nd:YAG laser technique, March (Ref. 11) recommends that a laser lens be used in performing a Nd:YAG laser iridectomy to aid in the placement of the lesion on the iris. He also recommends iridectomy placement beneath the upper lid if possible to avoid complications of halos, blurring, horizontal bands of light, and diplopia secondary to light transmission through the site postoperatively. Focusing on the ability of the Nd:YAG laser to produce a patent iridotomy, Spaeth (Ref. 11) reviewed a prospective study of 58 patients in which the right eyes were treated with the LASAG Microruptor 2 Nd:YAG laser and the left eyes with a Britt argon laser, and concluded that the Nd:YAG laser can indeed produce a patent iridotomy. He observed that there was a significant pressure rise in one third of the cases treated and that frequent hemorrhage occurred at the time of the iridectomy, but was not so severe that a gross hyphema developed. In no instance of Nd:YAG laser treatment was corneal endothelium or anterior lens capsule damage noted. Completion of the iridectomy was made on the basis of visualization of the lens through a hole in the iris. The IOP results reported for both lasers indicated a rise in IOP at 1 hour postoperative which decreased to the preoperative level 1 week postoperative.

In two studies by Robin and Pollack (Refs. 7 and 12) using the Coherent 9900 Q-switched and the AMO YAG-100 lasers, the authors reported that hyphema was not clinically significant and was consistent with other studies showing a lower incidence of bleeding for pretreated argon eyes. In one study, 33 eyes (both brown and blue irises) from 28 patients with pupillary block glaucoma were treated. Study followup was 1 month. Twenty-six had previous argon laser iridectomies. All had iridectomy closure within a week of argon treatment or there had been failure to penetrate the iris; the preoperative IOP range was 8 mm to 74 mm Hg and was 10 mm to 43 mm Hg at 1-month followup. Complications reported after use of the Coherent 9900 Q-switched Nd:YAG laser were focal discrete nonprogressive corneal endothelial changes in six eyes (18 percent), bleeding in 12 eyes (36 percent), and IOP greater than 10 mm Hg during the first 3 hours postoperatively in nine eyes (27 percent). No hyphema, laser-induced lens damage or retinal damage was observed. Two iridectomies closed within days of treatment. Study followup was 1 month.

In the second study, the authors studied 40 eyes (20 patients) in which one eye was treated with an argon laser and the fellow eye with a Q-switched YAG laser, an AMO YAG-100 (7 patients) or a Coherent JK prototype (13 patients). Iris colors were blue and brown. At no time was the IOP change significant between the argon laser and YAG laser treated patients. Inflammation was seen in all patients. Of the argon treated eyes, 12 had a rise in IOP during the first 3 hours postoperatively. Six (30 percent) iridectomies required retreatment, focal corneal opacities were seen in five (25 percent) of the argon treated eyes, and posterior synechiae were seen in three (15 percent) of the argon treated eyes. By comparison, thirteen YAG treated eyes had an IOP rise during the first 3 hours and bleeding occurred in nine (45 percent), with one having less than 5 percent hyphema which cleared by the first postoperative day. No iridectomy closures were seen, while focal corneal opacities were seen in seven (35 percent) of the YAG treated eyes. None of the YAG treated eyes suffered focal lenticular opacity. Finally, the Panel noted the publication by the American Academy of Ophthalmology, *Laser Peripheral Iridotomy for Pupillary-Block Glaucoma* (Ref. 2), which discusses surgical iridectomy and laser iridotomy techniques, treatment parameters, complications and patient care, and provides insight in addressing laser iridotomy and the above risks.

The Panel believes that the risks identified above that are directly attributable to the Nd:YAG laser for peripheral iridotomy can be controlled by special controls. The risks of damage to the corneal endothelium, the lens, or the retina are slight. These risks can be minimized by ensuring proper device design of the laser beam for accuracy and precision. The risk of IOP rise can be controlled by proper device labeling and by the surgeon through available, established medical procedures and treatments. There is reasonable assurance that an ophthalmic Nd:YAG laser (mode-locked or Q-switched) is safe and effective for iridotomy when the device is used consistent with appropriate labeling, designed in accordance with proper device specifications and produced under a quality assurance program to ensure that critical specifications are met within specified tolerances.

VIII. FDA's Tentative Findings

FDA tentatively concurs with the recommendation of the Panel that the Nd:YAG laser intended for peripheral iridotomy should be reclassified into class II and that the generic designation of the device be changed from Nd:YAG laser for posterior capsulotomy to Nd:YAG laser for posterior capsulotomy and peripheral iridotomy. The agency also tentatively concludes that ''new information'' in the form of publicly available, valid scientific evidence exists to provide reasonable assurance of the safety and effectiveness of the Nd:YAG laser for its intended use. Consistent with the purpose of the act, class II controls (labeling) as defined by section 513(a)(1)(B) of the act are sufficient to provide reasonable assurance that current Nd:YAG lasers are safe and effective for their intended use.

IX. Environmental Impact

The agency has determined under 21 CFR 25.24(e)(2) that thisaction is of a type that does not individually or cumulatively have a significant effect of the human environment. Therefore, neither as environmental assessment nor an environmental impact statement is required.

X. Analysis of Impacts

FDA has examined the impacts of the proposed rule under Executive Order 12866 and the Regulatory Flexibility Act (Pub. L. 96–354). Executive Order 12866 directs agencies to assess all costs and benefits of available regulatory alternatives and, when regulation is necessary, to select regulatory approaches that maximize net benefits (including potential economic, environmental, public health and safety, and other advantages; distributive impacts; and equity). The agency believes that this proposed rule is consistent with the regulatory philosophy and principles identified in the Executive Order. In addition, the proposed rule is not a significant regulatory action as defined by the Executive Order and so is not subject to review under the Executive Order.

The Regulatory Flexibility Act requires agencies to analyze regulatory options that would minimize any significant impact of a rule on small entities. Because reclassification of devices from class III into class II may relieve manufacturers of the cost of complying with the premarket approval requirements in section 515 of the act, and may permit small potential competitors to enter the marketplace by lowering their costs, the agency certifies that the final rule will not have a significant economic impact on a substantial number of small entities. Therefore, under the Regulatory Flexibility Act, no further analysis is required.

XI. Request for Comments

Interested persons may, on or before June 6, 1996, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m. Monday through Friday.

XII. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Reclassification Petition for the Nd:YAG Laser for Iridotomy, submitted by Intelligent Surgical Lasers, Inc., March 2, 1993.

2. American Academy of Ophthalmology Guideline: Laser Peripheral Iridotomy for Pupillary-Block Glaucoma, Approved by Board of Directors, June 25, 1988. (Also contained in the petition.)

3. Transcript of the Ophthalmic Devices Panel Meeting, October 28, 1993.

4. Del Priore, L. V., A. L. Robin, and I. P. Pollack, ''Neodymium:YAG and Argon Laser Iridotomy: Long-term Followup in a Prospective, Randomized Clinical Trial,'' *Ophthalmology*, 94(9):1205–1211, 1988.

5. Fleck, B. W., E. Wright, C. McGlynn, ''Argon Laser Pretreatment 4 to 6 Weeks Before Nd:YAG Laser Iridotomy,'' *Ophthalmic Surgery*, 22(11):644–649, 1991.

6. Goins, K., E. Schmeisser, T. Smith, ''Argon Laser in Nd:YAG Iridotomy,'' *Ophthalmic Surgery*, 21(7):497–500, 1990.

7. Robin, A. L. and I. P. Pollack, ''Q-switched Neodymium-YAG Laser Iridotomy in Patients in Whom the Argon Laser Fails,'' *Archives of Ophthalmology*, 104(4):531–535, 1986.

8. McGalliard, J. N., P. K. Wishart, ''The Effect of Nd:YAG Iridotomy on Intraocular Pressure in Hypertensive Eyes with Shallow Anterior Chambers,'' *Eye*, 4(6):823–829, 1990.

9. Jiang, Y. Q., ''The Long-term Effect of Nd:YAG Laser Iridotomy,'' Chung-Hua Yn Ko Tsa Chih Chin, *Journal of Ophthalmology*, 27(4):221–224, 1991.

10. Romano, J. H., R. A. Hitchings, and D. Pooinasawmy, ''Role of Nd:YAG Peripheral Iridectomy in the Management of Ocular Hypertension With a Narrow Angle,'' *Ophthalmic Surgery*, 19(11):814–816, 1988.

11. March, W. F., and G. Spaeth, ''YAG Laser Iridectomy, Complications,'' *Ophthalmic Lasers (A Second Generation)*, Thorogare, New York: Slack Inc., 1990.

12. Robin, A. L. and I. P. Pollack, ''A Comparison of Neodymium:YAG and Argon Laser Iridotomies,'' *Ophthalmology*, 91(9):1011–1016, 1984.

13. Moster, M. R., et al., ''Laser Iridectomy, A Controlled Study Comparing Argon and Neodymium:YAG,'' *Ophthalmology*, 93:20–24, 1986.

14. Cinotti, D. J., et al., ''Neodymium:YAG Laser Therapy for Pseudophakic Pupillary Block,'' *Journal of Cataract and Refractive Surgery*, 12:174–179, 1986.

15. Robin, A. L. et al, ''Q-switched Neodymium-YAG Iridotomy: A Field Trial with a Portable Laser System,'' *Archives of Ophthalmology*, 104:526–530, 1986.

List of Subjects in 21 CFR Part 886

Medical devices, Ophthalmic goods and services.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 886 be amended as follows:

PART 886—OPHTHALMIC DEVICES

1. The authority citation for 21 CFR part 886 continues to read as follows:

Authority: Secs. 501, 510, 513, 515, 520, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351, 360, 360c, 360e, 360j, 371).

2. Section 886.4392 is amended by revising the section heading and paragraph (a) to read as follows:

§ 886.4392 Nd:YAG laser for posterior capsulotomy and peripheraliridotomy.

(a) *Identification*. The Nd:YAG laser for posterior capsulotomy and peripheral iridotomy consists of a mode-locked or Q-switched solid state Nd:YAG laser intended for disruption of the posterior capsule or the iris via optical breakdown. The Nd:YAG laser generates short pulse, low energy, high power, coherent optical radiation. When the laser output is combined with focusing optics, the high irradiance at the target causes tissue disruption via optical breakdown. A visible aiming system is utilized to target the invisible Nd:YAG laser radiation on or in close proximity to the target tissue.

* * * * *

Dated: February 14, 1996.

D.B. Burlington,

Director, Center for Devices and Radiological Health.

[FR Doc. 96–5445 Filed 3–7–96; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[INTL–0054–95]

RIN 1545–AT96

Proposed Amendments to the Regulations on the Determination of Interest Expense Deduction of Foreign Corporations and Branch Profits Tax

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking and notice of public hearing.

SUMMARY: This document contains proposed Income Tax Regulations relating to the determination of the interest expense deduction of foreign corporations under section 882 and the branch profits tax under section 884 of the Internal Revenue Code of 1986. These proposed regulations are necessary to provide guidance that coordinates with guidance provided in final regulations under sections 882 and 884 published elsewhere in this issue of the Federal Register. These regulations will affect foreign corporations engaged in a U.S. trade or business. This document also provides notice of a public hearing on these proposed regulations.