test the keenness of ophthalmic surgical knives to determine whether re-
sharpening is needed.

(b) Classification. Class I (general controls). The device is exempt from the
premarket notification procedures in subpart E of part 807 of this chapter,
subject to the limitations in §886.9. The device is also exempt from the current
good manufacturing practice requirements of the quality system regulation
in part 820 of this chapter, with the exceptiion of §820.180, with respect to gen-
eral requirements concerning records, and §820.198, with respect to complaint
files.

[52 FR 33355, Sept. 2, 1987, as amended at 53
FR 35606, Sept. 14, 1988; 66 FR 38813, July 25,
2001]

§ 886.4250 Ophthalmic electrolysis
unit.

(a) Identification. An ophthalmic elec-
trolysis unit is an AC-powered or bat-
tery-powered device intended to de-
stroy ocular hair follicles by applying a
galvanic electrical current.

(b) Classification. Class I for the bat-
tery-powered device. Class II for the
AC-powered device. The battery-pow-
ered device is exempt from the pre-
market notification procedures in sub-
part E of part 807 of this chapter, sub-
ject to the limitations in §886.9.

[55 FR 48443, Nov. 20, 1990, as amended at 59
FR 63013, Dec. 7, 1994; 66 FR 38813, July 25,
2001]

§ 886.4270 Intraocular gas.

(a) Identification. An intraocular gas
is a device consisting of a gaseous fluid
intended to be introduced into the eye
to place pressure on a detached retina.

(b) Classification. Class III.

(c) Date PMA or notice of completion of
a PDP is required. As of May 28, 1976, an
approval under section 515 of the act is
required before this device may be
commercially distributed. See §886.3.

§ 886.4275 Intraocular fluid.

(a) Identification. An intraocular fluid
is a device consisting of a nongaseous
fluid intended to be introduced into the
eye to aid performance of surgery, such
as to maintain anterior chamber depth,
preserve tissue integrity, protect tissue
from surgical trauma, or function as a
tamponade during retinal reattach-
ment.

(b) Classification. Class III.

(c) Date PMA or notice of completion of
a PDP is required. As of May 28, 1976, an
approval under section 515 of the act is
required before this device may be
commercially distributed. See §886.3.

§ 886.4280 Intraocular pressure meas-
uring device.

(a) Identification. An intraocular pres-
sure measuring device is a manual or
AC-powered device intended to measure
intraocular pressure. Also included
are any devices found by FDA to be
substantially equivalent to such de-
vices. Accessories for the device may
include calibrators or recorders. The
device is intended for use in the diag-
agnosis of glaucoma.

(b) Classification. Class III.

(c) Date PMA or notice of completion of
PDP is required. As of May 28, 1976, an
approval under section 515 of the act is
required before this device may be
commercially distributed. See §886.3.

§ 886.4300 Intraocular lens guide.

(a) Identification. An intraocular lens
guide is a device intended to be in-
serted into the eye during surgery to
direct the insertion of an intraocular
lens and be removed after insertion is
completed.

(b) Classification. Class I (general con-
trols). Except when used as folders or
injectors for soft or foldable intra-
ocular lenses, the device is exempt
from the premarket notification proce-
dures in subpart E of part 807 of this
chapter subject to §886.9.

[52 FR 33355, Sept. 2, 1987, as amended at 65
FR 2321, 2000]

§ 886.4335 Operating headlamp.

(a) Identification. An operating headlamp is an AC-powered or battery-
powered device intended to be worn on
the user’s head to provide a light
source to aid visualization during sur-
gical, diagnostic, or therapeutic proce-
dures.

(b) Classification. Class I for the bat-
tery-powered device. Class II for the