

reviewing the rulemaking record for the OLPP final rule, AMS discovered a significant, material error in the mathematical calculation of the benefits estimates. With the material error, the regulatory impact analysis presented costs and benefits in a table that could be reasonably interpreted to conclude that benefits were likely to exceed the costs. (82 FR 7083–82 FR 7084.) However, AMS believes that the regulatory impact analysis' calculation of benefits was flawed because the incorrect calculation was applied for the 3 percent and 7 percent discount rates. Re-analysis using the correct mathematical calculations suggests that this error was material. It is not appropriate for AMS to allow a final rule to become effective based on a record containing such a material error. AMS intends to seek public comment on the revised calculation of benefits.

Due to these significant concerns regarding statutory authority for, and costs and benefits of, the OLPP rule, including the question whether the OLPP final rule was based on a mathematically flawed assessment of benefits, AMS is selecting Option 3: Delay. AMS is issuing this final rule to further delay the effective date for until May 14, 2018 to allow for AMS to issue another notice of proposed rulemaking to receive comments on USDA statutory authority under the OPFA to regulate animal welfare; the likely costs and benefits of the OLPP rule viewed in terms of the statutory objectives of the OPFA, as interpreted above; whether the OLPP rule's requirements represent the most innovate and least burdensome way to achieve regulatory ends; and the revised calculations and analysis of the benefits of the OLPP rule. This delay will provide additional time for AMS to solicit comment on these important issues and review all the comments prior to making a final decision on the direction of the OLPP final rule.

To preserve the status quo rather than allow an expansive set of new requirements to become effective only to be delayed, suspended, or withdrawn a short time later and to allow AMS to receive and consider comments on the issues discussed above, this final rule action is effective upon publication because AMS believes that the 30-day delay is impracticable, unnecessary, and contrary to the public interest. When agencies establish good cause for an immediate effective date, Congress intended that, combined with unavoidable time limitations, "the primary consideration was to be the 'convenience or necessity of the people affected.'" *United States v. Gavrilovic*, 551 F.2d 1099, 1104 (8th Cir. 1977)

(citing S.Rep.No.752, 79th Cong., 1st Sess. 15 (1946); H.R.Rep.No.1980, 79th Cong., 2d Sess. 25 (1946)). Ordinarily, the thirty-day waiting period gives stakeholders and the public a reasonable time to adjust behavior. *Omnipoint Corp. v. F.C.C.*, 78 F.3d 620, 630 (D.C. Cir. 1996). In this case, however, a thirty-day waiting period would require stakeholders to begin changing their behavior to comply with the OLPP final rule, when that rule may be delayed, suspended, or withdrawn after the agency has completed review of comments in response to an notice of proposed rulemaking that will present the issues discussed above. It is also contrary to the public interest to allow a final rule that is based on a flawed record to become effective. Thus, and for the reasons stated above, waiting for thirty days to delay the effective date of the OLPP final rule is not warranted by "convenience" and would be unnecessary and contrary to the public interest.

Dated: November 8, 2017.

**Sonia N. Jimenez,**

*Acting Associate Administrator, Agricultural Marketing Service.*

[FR Doc. 2017-24675 Filed 11-9-17; 8:45 am]

**BILLING CODE 3410-02-P**

## DEPARTMENT OF TRANSPORTATION

### Federal Aviation Administration

#### 14 CFR Part 39

**[Docket No. FAA-2017-0712; Product Identifier 2017-NM-014-AD; Amendment 39-19095; AD 2017-23-01]**

**RIN 2120-AA64**

#### **Airworthiness Directives; Bombardier, Inc., Airplanes**

**AGENCY:** Federal Aviation Administration (FAA), Department of Transportation (DOT).

**ACTION:** Final rule.

**SUMMARY:** We are superseding Airworthiness Directive (AD) 2016-13-14, which applied to certain Bombardier, Inc., Model DHC-8-400 series airplanes. AD 2016-13-14 required an inspection to determine if certain left and right main landing gear (MLG) retract actuator rod ends were installed, repetitive liquid penetrant inspections (LPIs) of affected left and right MLG retract actuator rod ends, and corrective actions if necessary. This new AD retains the actions specified in AD 2016-13-14 and also requires replacement of the left and right MLG retract actuator rod ends. This AD was

prompted by a report of a cracked MLG retract actuator rod end. We are issuing this AD to address the unsafe condition on these products.

**DATES:** This AD is effective December 19, 2017.

The Director of the Federal Register approved the incorporation by reference of a certain publication listed in this AD as of July 20, 2016 (81 FR 43481, July 5, 2016).

**ADDRESSES:** For service information identified in this final rule, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone: 416-375-4000; fax: 416-375-4539; email: [thd.qseries@aero.bombardier.com](mailto:thd.qseries@aero.bombardier.com); Internet: <http://www.bombardier.com>. You may view this referenced service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425-227-1221. It is also available on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0712.

#### **Examining the AD Docket**

You may examine the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA-2017-0712; or in person at the Docket Management Facility between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays. The AD docket contains this AD, the regulatory evaluation, any comments received, and other information. The address for the Docket Office (telephone: 800-647-5527) is Docket Management Facility, U.S. Department of Transportation, Docket Operations, M-30, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue SE., Washington, DC 20590.

**FOR FURTHER INFORMATION CONTACT:** Aziz Ahmed, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516-228-7329; fax: 516-794-5531.

#### **SUPPLEMENTARY INFORMATION:**

##### **Discussion**

We issued a notice of proposed rulemaking (NPRM) to amend 14 CFR part 39 to supersede AD 2016-13-14, Amendment 39-18579 (81 FR 43481, July 5, 2016) ("AD 2016-13-14"). AD 2016-13-14 applied to certain Bombardier, Inc., Model DHC-8-400 series airplanes. The NPRM published in the **Federal Register** on July 28, 2017

(82 FR 35127). The NPRM was prompted by a report of a cracked MLG retract actuator rod end. The NPRM proposed to continue to require the actions specified in AD 2016–13–14. The NPRM also proposed to require replacement of the left and right MLG retract actuator rod ends. We are issuing this AD to detect and correct fatigue cracking of the left and right MLG retract actuator rod ends, which could lead to left or right MLG collapse.

Transport Canada Civil Aviation (TCCA), which is the aviation authority for Canada, has issued Canadian AD CF–2016–16R1, dated June 27, 2016 (referred to after this as the Mandatory Continuing Airworthiness Information, or “the MCAI”), to correct an unsafe condition for certain Bombardier, Inc. Model DHC–8–400 series airplanes. The MCAI states:

There has been a single reported case of a cracked MLG retract actuator rod end in service. A supplier disclosure letter and subsequent Bombardier analysis indicate that the MLG retract actuator rod end P/N [part number] P3A2750 and P3A2750–1 may develop fatigue cracking. This condition, if not corrected, could lead to left hand (LH) or right hand (RH) MLG collapse.

This [Canadian] AD mandates the inspection [to determine if certain left and right main landing gear MLG retract actuator rod ends are installed, repetitive LPis of affected left and right MLG retract actuator rod ends, and corrective actions if necessary], and replacement of the LH and RH MLG retract actuator rod ends P/N P3A2750 and P3A2750–1 [which is terminating action for the repetitive LPis].

This [Canadian] AD was revised to clarify paragraph B. and C. [of this Canadian AD], which specifies when the Liquid Penetrant Inspections (LPI) should begin.

Corrective actions include replacing cracked MLG retract actuator rod ends. You may examine the MCAI in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2017–0712.

### Comments

We gave the public the opportunity to participate in developing this AD. We received no comments on the NPRM or on the determination of the cost to the public.

### Conclusion

We reviewed the available data and determined that air safety and the public interest require adopting this AD as proposed except for minor editorial changes. We have determined that these minor changes:

- Are consistent with the intent that was proposed in the NPRM for correcting the unsafe condition; and

- Do not add any additional burden upon the public than was already proposed in the NPRM.

### Related Service Information Under 1 CFR Part 51

Bombardier, Inc., has issued Bombardier Service Bulletin 84–32–142, dated May 4, 2016. This service information describes procedures for an inspection to determine if certain left and right MLG retract actuator rod ends are installed, repetitive LPis of the left and right MLG retract actuator rod ends, and replacement of left and right MLG retract actuator rod ends. This service information is reasonably available because the interested parties have access to it through their normal course of business or by the means identified in the ADDRESSES section.

### Costs of Compliance

We estimate that this AD affects 52 airplanes of U.S. registry.

We estimate the following costs to comply with this AD:

The actions required by AD 2016–13–14, and retained in this AD, take about 1 work-hour per product, at an average labor rate of \$85 per work-hour. Based on these figures, the estimated cost of the inspection that is required by AD 2016–13–14 is \$85 per product.

We also estimate that it will take about 3 work-hours per product to comply with the basic requirements of this AD. The average labor rate is \$85 per work-hour. Required parts will cost about \$2,019 per product. Based on these figures, we estimate the cost of this AD on U.S. operators to be \$118,248, or \$2,274 per product.

In addition, we estimate that any necessary follow-on actions will take about 3 work-hours and require parts costing \$2,019, for a cost of \$2,274 per product. We have no way of determining the number of aircraft that might need these actions.

According to the manufacturer, some of the costs of this AD may be covered under warranty, thereby reducing the cost impact on affected individuals. We do not control warranty coverage for affected individuals. As a result, we have included all available costs in our cost estimate.

### Authority for This Rulemaking

Title 49 of the United States Code specifies the FAA’s authority to issue rules on aviation safety. Subtitle I, section 106, describes the authority of the FAA Administrator. “Subtitle VII: Aviation Programs,” describes in more detail the scope of the Agency’s authority.

We are issuing this rulemaking under the authority described in “Subtitle VII, Part A, Subpart III, Section 44701: General requirements.” Under that section, Congress charges the FAA with promoting safe flight of civil aircraft in air commerce by prescribing regulations for practices, methods, and procedures the Administrator finds necessary for safety in air commerce. This regulation is within the scope of that authority because it addresses an unsafe condition that is likely to exist or develop on products identified in this rulemaking action.

This AD is issued in accordance with authority delegated by the Executive Director, Aircraft Certification Service, as authorized by FAA Order 8000.51C. In accordance with that order, issuance of ADs is normally a function of the Compliance and Airworthiness Division, but during this transition period, the Executive Director has delegated the authority to issue ADs applicable to transport category airplanes to the Director of the System Oversight Division.

### Regulatory Findings

We determined that this AD will not have federalism implications under Executive Order 13132. This AD will not have a substantial direct effect on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government.

For the reasons discussed above, I certify that this AD:

1. Is not a “significant regulatory action” under Executive Order 12866;
2. Is not a “significant rule” under the DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979);
3. Will not affect intrastate aviation in Alaska; and
4. Will not have a significant economic impact, positive or negative, on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

### List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

### Adoption of the Amendment

Accordingly, under the authority delegated to me by the Administrator, the FAA amends 14 CFR part 39 as follows:

### PART 39—AIRWORTHINESS DIRECTIVES

- 1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

### § 39.13 [Amended]

■ 2. The FAA amends § 39.13 by removing Airworthiness Directive (AD) 2016–13–14, Amendment 39–18579 (81 FR 43481, July 5, 2016), and adding the following new AD:

**2017–23–01 Bombardier, Inc.:** Amendment 39–19095; Docket No. FAA–2017–0712; Product Identifier 2017–NM–014–AD.

#### (a) Effective Date

This AD is effective December 19, 2017.

#### (b) Affected ADs

This AD replaces AD 2016–13–14, Amendment 39–18579 (81 FR 43481, July 5, 2016) (“AD 2016–13–14”).

#### (c) Applicability

This AD applies to Bombardier, Inc., Model DHC–8–400, –401 and –402 airplanes, certificated in any category, serial numbers 4001, and 4003 through 4325 inclusive.

#### (d) Subject

Air Transport Association (ATA) of America Code 32, Landing gear.

#### (e) Reason

This AD was prompted by a report of a cracked main landing gear (MLG) retract actuator rod end. We are issuing this AD to detect and correct fatigue cracking of the left and right MLG retract actuator rod ends, which could lead to left or right MLG collapse.

#### (f) Compliance

Comply with this AD within the compliance times specified, unless already done.

#### (g) Retained Part Number Inspection, With No Changes

This paragraph restates the requirements of paragraph (g) of AD 2016–13–14, with no changes. Within 100 flight cycles after July 20, 2016 (the effective date of AD 2016–13–14), inspect the left and right MLG retract actuator rod ends to determine if part number (P/N) P3A2750 or P3A2750–1 is installed. A review of airplane maintenance records is acceptable in lieu of this inspection if the part number can be conclusively determined from that review.

#### (h) Retained Repetitive Liquid Penetrant Inspections (LPIs), With No Changes

This paragraph restates the requirements of paragraph (h) of AD 2016–13–14, with no changes. For each left or right MLG retract actuator rod end having P/N P3A2750 or P3A2750–1: At the applicable time specified in paragraph (h)(1) or (h)(2) of this AD, do an LPI to detect cracks of the MLG retract actuator rod end, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD. Thereafter, repeat the LPI at intervals not to exceed 600 flight cycles.

(1) If the MLG retract actuator rod end has accumulated more than 6,000 flight cycles as of July 20, 2016 (the effective date of AD

2016–13–14); Inspect within 100 flight cycles after July 20, 2016.

(2) If the MLG retract actuator rod end has accumulated 6,000 flight cycles or fewer as of July 20, 2016 (the effective date of AD 2016–13–14); Inspect within 600 flight cycles after July 20, 2016.

#### (i) Retained Corrective Action, With No Changes

This paragraph restates the requirements of paragraph (i) of AD 2016–13–14, with no changes. If any crack is found during any inspection required by paragraph (h) of this AD, before further flight, replace the cracked MLG retract actuator rod end, P/N P3A2750 or P3A2750–1, with a MLG retract actuator rod end, P/N P3A6460, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD.

#### (j) Retained Optional Replacement, With No Changes

This paragraph restates the optional replacement specified in paragraph (j) of AD 2016–13–14, with no changes. Replacement of the left and right side MLG retract actuator rod ends, P/N P3A2750 or P3A2750–1, with left and right MLG retract actuator rod ends, P/N P3A6460, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD, constitutes terminating action for the actions required by paragraphs (g) and (h) of this AD for that airplane.

#### (k) Retained Exception, With No Changes

This paragraph restates the requirements of paragraph (k) of AD 2016–13–14, with no changes. If it is not possible to complete all the instructions in Bombardier Service Bulletin 84–32–142, dated May 4, 2016, because of the configuration of the airplane: Before further flight, repair using a method approved by the Manager, New York ACO Branch, FAA; or Transport Canada Civil Aviation (TCCA); or Bombardier, Inc.’s TCCA Design Approval Organization (DAO).

#### (l) Retained Parts Installation Prohibition, With No Changes

This paragraph restates the requirements of paragraph (l) of AD 2016–13–14, with no changes. As of July 20, 2016 (the effective date of AD 2016–13–14), no person may install a left or right MLG retract actuator rod end, P/N P3A2750 or P3A2750–1, on any airplane.

#### (m) New Requirement of This AD: Replacement

Within 1,800 flight cycles after accomplishing the initial inspection required by paragraph (g) of this AD, replace the left and right side MLG retract actuator rod ends having P/N P3A2750 or P3A2750–1, with left and right MLG retract actuator rod ends having P/N P3A6460, in accordance with the Accomplishment Instructions of Bombardier Service Bulletin 84–32–142, dated May 4, 2016, except as required by paragraph (k) of this AD. Accomplishing this replacement terminates the requirements of paragraphs (g) and (h) of this AD for that airplane.

#### (n) Other FAA AD Provisions

The following provisions also apply to this AD:

(1) *Alternative Methods of Compliance (AMOCs):* The Manager, New York ACO Branch, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the certification office, send it to ATTN: Program Manager, Continuing Operational Safety, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7300; fax: 516–794–5531. Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(2) *Contacting the Manufacturer:* For any requirement in this AD to obtain corrective actions from a manufacturer, the action must be accomplished using a method approved by the Manager, New York ACO Branch, FAA; or TCCA; or Bombardier Inc.’s TCCA DAO. If approved by the DAO, the approval must include the DAO-authorized signature.

#### (o) Related Information

(1) Refer to Mandatory Continuing Airworthiness Information (MCAI) Canadian AD CF–2016–16R1, dated June 27, 2016, for related information. This MCAI may be found in the AD docket on the Internet at <http://www.regulations.gov> by searching for and locating Docket No. FAA–2017–0712.

(2) For more information about this AD, contact Aziz Ahmed, Aerospace Engineer, Airframe and Mechanical Systems Section, FAA, New York ACO Branch, 1600 Stewart Avenue, Suite 410, Westbury, NY 11590; telephone: 516–228–7329; fax: 516–794–5531.

#### (p) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless this AD specifies otherwise.

(3) The following service information was approved for IBR on July 20, 2016 (81 FR 43481, July 5, 2016).

(i) Bombardier Service Bulletin 84–32–142, dated May 4, 2016.

(ii) Reserved.

(4) For service information identified in this AD, contact Bombardier, Inc., Q-Series Technical Help Desk, 123 Garratt Boulevard, Toronto, Ontario M3K 1Y5, Canada; telephone: 416–375–4000; fax: 416–375–4539; email: [thd.qseries@aero.bombardier.com](mailto:thd.qseries@aero.bombardier.com); Internet: <http://www.bombardier.com>.

(5) You may view this service information at the FAA, Transport Standards Branch, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(6) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202-741-6030, or go to: <http://www.archives.gov/federal-register/cfr/ibr-locations.html>.

Issued in Renton, Washington, on October 30, 2017.

**Jeffrey E. Duven,**

*Director, System Oversight Division, Aircraft Certification Service.*

[FR Doc. 2017-24166 Filed 11-13-17; 8:45 am]

**BILLING CODE 4910-13-P**

## TENNESSEE VALLEY AUTHORITY

### 18 CFR Part 1301

#### Privacy Act Regulations; Correction

##### *Correction*

In rule document 2017-24300, appearing on pages 51757-51758 in the issue of Wednesday, November 8, 2017, make the following correction:

■ On page 51757 in the second column, remove Amendatory instruction 2.

*Dates:* This correction is effective on November 8, 2017.

[FR Doc. C1-2017-24300 Filed 11-9-17; 4:15 pm]

**BILLING CODE 1301-00-D**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 866

[Docket No. FDA-2017-N-5881]

#### Medical Devices; Immunology and Microbiology Devices; Classification of the Automated Indirect Immunofluorescence Microscope and Software-Assisted System

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the automated indirect immunofluorescence microscope and software-assisted system into class II (special controls). The special controls that apply to the device type are identified in this order and will be part of the codified language for the automated indirect immunofluorescence microscope and software-assisted system's classification. We are taking this action because we have determined that classifying the device into class II

(special controls) will provide a reasonable assurance of safety and effectiveness of the device. We believe this action will also enhance patients' access to beneficial innovative devices, in part by reducing regulatory burdens.

**DATES:** This order is effective November 14, 2017. The classification was applicable on April 9, 2015.

**FOR FURTHER INFORMATION CONTACT:** Steven Tjoe, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4550, Silver Spring, MD 20993-0002, 301-796-5866, [steven.tjoe@fda.hhs.gov](mailto:steven.tjoe@fda.hhs.gov).

#### **SUPPLEMENTARY INFORMATION:**

##### **I. Background**

Upon request, FDA has classified the automated indirect immunofluorescence microscope and software-assisted system as class II (special controls), which we have determined will provide a reasonable assurance of safety and effectiveness. In addition, we believe this action will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens by placing the device into a lower device class than the automatic class III assignment.

The automatic assignment of class III occurs by operation of law and without any action by FDA, regardless of the level of risk posed by the new device. Any device that was not in commercial distribution before May 28, 1976, is automatically classified as, and remains within, class III and requires premarket approval unless and until FDA takes an action to classify or reclassify the device (see 21 U.S.C. 360c(f)(1)). We refer to these devices as "postamendments devices" because they were not in commercial distribution prior to the date of enactment of the Medical Device Amendments of 1976, which amended the Federal Food, Drug, and Cosmetic Act (the FD&C Act).

FDA may take a variety of actions in appropriate circumstances to classify or reclassify a device into class I or II. We may issue an order finding a new device to be substantially equivalent under section 513(i) of the FD&C Act (21 U.S.C. 360c(i)) to a predicate device that does not require premarket approval. We determine whether a new device is substantially equivalent to a predicate by means of the procedures for premarket notification under section 510(k) of the FD&C Act and part 807 (21 U.S.C. 360(k) and 21 CFR part 807, respectively).

FDA may also classify a device through "De Novo" classification, a common name for the process authorized under section 513(f)(2) of the

FD&C Act. Section 207 of the Food and Drug Administration Modernization Act of 1997 established the first procedure for De Novo classification (Pub. L. 105-115). Section 607 of the Food and Drug Administration Safety and Innovation Act modified the De Novo application process by adding a second procedure (Pub. L. 112-144). A device sponsor may utilize either procedure for De Novo classification.

Under the first procedure, the person submits a 510(k) for a device that has not previously been classified. After receiving an order from FDA classifying the device into class III under section 513(f)(1) of the FD&C Act, the person then requests a classification under section 513(f)(2).

Under the second procedure, rather than first submitting a 510(k) and then a request for classification, if the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence, that person requests a classification under section 513(f)(2) of the FD&C Act.

Under either procedure for De Novo classification, FDA is required to classify the device by written order within 120 days. The classification will be according to the criteria under section 513(a)(1) of the FD&C Act. Although the device was automatically placed within class III, the De Novo classification is considered to be the initial classification of the device.

We believe this De Novo classification will enhance patients' access to beneficial innovation, in part by reducing regulatory burdens. When FDA classifies a device into class I or II via the De Novo process, the device can serve as a predicate for future devices of that type, including for 510(k)s (see 21 U.S.C. 360c(f)(2)(B)(i)). As a result, other device sponsors do not have to submit a De Novo request or premarket approval application (PMA) in order to market a substantially equivalent device (see 21 U.S.C. 360c(i), defining "substantial equivalence"). Instead, sponsors can use the less-burdensome 510(k) process, when necessary, to market their device.

##### **II. De Novo Classification**

For this device, FDA issued an order on November 14, 2014, finding the NOVA View® Automated Fluorescence Microscope not substantially equivalent to a predicate not subject to PMA. Thus, the device remained in class III in accordance with section 513(f)(1) of the FD&C Act when we issued the order.

On December 11, 2014, Inova Diagnostics, Inc. submitted a request for De Novo classification of the NOVA