

the ground or flight path in normal taxi and flight attitudes of the airplane. This means must be designed to function, without continuous attention on the part of the flightcrew, in conditions from light misting precipitation to heavy rain, at speeds from fully stopped in still air, to 1.5 V<sub>SR1</sub> with lift and drag devices retracted.

Issued in Renton, Washington, on March 27, 2015.

**Michael Kazyski,**

*Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.*

[FR Doc. 2015-07713 Filed 4-3-15; 8:45 am]

**BILLING CODE 4910-13-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 14

[Docket No. FDA-2009-N-0443]

#### Advisory Committee; Anti-Infective Drugs Advisory Committee

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

**ACTION:** Final rule.

**SUMMARY:** The Food and Drug Administration (FDA) is amending the standing advisory committees' regulations to change the name of the Anti-Infective Drugs Advisory Committee. This action is being taken to change the name of this committee on the Agency's list of standing advisory committees.

**DATES:** This rule is effective April 6, 2015. The name change became applicable March 4, 2015.

**FOR FURTHER INFORMATION CONTACT:** Michael Ortwerth, Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5129, Silver Spring, MD 20993-0002, FAX: 301-847-8640, or *Michael.Ortwerth@fda.hhs.gov*.

**SUPPLEMENTARY INFORMATION:** The Anti-Infective Drugs Advisory Committee (the Committee) was established on October 7, 1980 (45 FR 79025). The Committee reviews and evaluates available data concerning the safety and effectiveness of marketed and investigational human drug products for use in the treatment of infectious diseases and disorders.

The Committee name has been changed to the following: Antimicrobial Drugs Advisory Committee. The Agency changed the name to better reflect the

products and issues that will be brought to the committee. The change became effective March 4, 2015.

Therefore, the Agency is amending 21 CFR 14.100(c) as set forth in the regulatory text of this document.

Under 5 U.S.C. 553(b)(3)(B) and (d) and 21 CFR 10.40(d) and (e), the Agency finds good cause to dispense with notice and public comment procedures and to proceed to an immediate effective date on this rule. Notice and public comment and a delayed effective date are unnecessary and are not in the public interest as this final rule merely removes the name of the Anti-Infective Drugs Advisory Committee from the list of standing advisory committees in 21 CFR 14.100 and replaces it with the Antimicrobial Drugs Advisory Committee.

#### List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

#### PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

■ 1. The authority citation for 21 CFR part 14 continues to read as follows:

**Authority:** 5 U.S.C. App. 2; 15 U.S.C. 1451-1461; 21 U.S.C. 41-50, 141-149, 321-394, 467f, 679, 821, 1034; 28 U.S.C. 2112; 42 U.S.C. 201, 262, 263b, 264; Pub. L. 107-109; Pub. L. 108-155; Pub. L. 113-54.

■ 2. Amend § 14.100 by revising paragraph (c)(2) introductory text to read as follows:

#### § 14.100 List of standing advisory committees.

\* \* \* \* \*

(c) \* \* \*

(2) *Antimicrobial Drugs Advisory Committee.*

\* \* \* \* \*

Dated: March 27, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

[FR Doc. 2015-07789 Filed 4-3-15; 8:45 am]

**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

#### 21 CFR Part 876

[Docket No. FDA-2015-N-0804]

#### Medical Devices; Gastroenterology-Urology Devices; Classification of the Urethral Insert With Pump for Bladder Drainage

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA) is classifying the urethral insert with pump for bladder drainage into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the urethral insert with pump for bladder drainage's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

**DATES:** This order is effective April 6, 2015. The classification was applicable on October 14, 2014.

**FOR FURTHER INFORMATION CONTACT:** John Baxley, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G210, Silver Spring, MD 20993-0002, 301-796-6549.

#### SUPPLEMENTARY INFORMATION:

##### I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as postamendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.