rules can be found at 82 FR 44982 (September 27, 2017).

**Regulatory Analysis of Amendments to the Commission’s Rules**

The Commission certifies that these amendments to the Commission’s rules will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) because it does not create an economic impact and does not affect small entities. The amendments are concerned only with the administration of Privacy Act systems of records within the Commission.

The amendments to the Commission’s rules do not contain any information collection requirements subject to the provisions of the Paperwork Reduction Act (44 U.S.C. 3501 et seq.).

No actions are necessary under title II of the Unfunded Mandates Reform Act of 1995, Public Law 104–4 (2 U.S.C. 1531–1538) because the amendments to the Commission’s rules will not result in the expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year (adjusted annually for inflation), and will not significantly or uniquely affect small governments.

The Commission has determined that these rules do not meet the criteria described in section 3(f) of Executive Order 12866 (58 FR 51735, October 4, 1993) and thus do not constitute a “significant regulatory action” for purposes of the Executive Order.

The amendments to the Commission’s rules do not have Federalism implications warranting the preparation of a federalism summary impact statement under Executive Order 13132 (64 FR 43255, August 10, 1999).

The amendments to the Commission’s rules are not “major rules” as defined by section 251 of the Small Business Regulatory Enforcement Fairness Act of 1996 (5 U.S.C. 801 et seq.).

**List of Subjects in 19 CFR Part 201**

Administrative practice and procedure.

For the reasons stated in the preamble, under the authority of 19 U.S.C. 1335, the United States International Trade Commission amends 19 CFR part 201 as follows:

**PART 201—RULES OF GENERAL APPLICATION**

1. The authority citation for part 201 continues to read as follows:

   **Authority:** 19 U.S.C. 1335; 19 U.S.C. 2482, unless otherwise noted.

2. In §201.32, remove paragraphs (a) and (b); redesignate paragraph (c) as paragraph (a); revise the first sentence of newly redesignated paragraph (a); and add paragraph (b) to read as follows:

   **§201.32 Specific exemptions.**

   (a) Pursuant to 5 U.S.C. 552a(k)(1), (5) and (6), records contained in the system entitled “Personnel Security Investigative Files” have been exempted from subsections (c)(3), (d), (e)(1), (e)(4)(G) through (I) and (f) of the Privacy Act. * * * *

   (b) Pursuant to 5 U.S.C. 552a(k)(1) and (k)(2), records contained in the system entitled “Freedom of Information Act and Privacy Act Records” have been exempted from subsections (c)(3), (d), (e)(1), (e)(4)(G) through (I) and (f) of the Privacy Act. Pursuant to section 552a(k)(1) of the Privacy Act, the Commission exempts records that contain properly classified information pertaining to national defense or foreign policy. Application of exemption (k)(1) may be necessary to preclude individuals’ access to or amendment of such classified information under the Privacy Act. Pursuant to section 552a(k)(2) of the Privacy Act, and in order to protect the effectiveness of Inspector General investigations by preventing individuals who may be the subject of an investigation from obtaining access to the records and thus obtaining the opportunity to conceal or destroy evidence or to intimidate witnesses, the Commission exempts records insofar as they include investigatory material compiled for law enforcement purposes. However, if any individual is denied any right, privilege, or benefit to which he is otherwise entitled under Federal law due to the maintenance of this material, such material shall be provided to such individual except to the extent that the disclosure of such material would reveal the identity of a source who furnished information to the Government under an express promise that the identity of the source would be held in confidence.

   By order of the Commission.


   Lisa R. Barton,
   Secretary to the Commission.

   [FR Doc. 2017–27671 Filed 12–22–17; 8:45 am]

   **BILLING CODE 7020–02–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 868**

[Docket No. FDA–2017–N–6568]

**Medical Devices; Anesthesiology Devices; Classification of the External Negative Pressure Airway Aid**

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

**ACTION:** Final order.

**SUMMARY:** The Food and Drug Administration (FDA or we) is classifying the external negative pressure airway aid 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 external negative pressure airway aid’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 December 26, 2017. The classification was applicable on December 23, 2015.

**FOR FURTHER INFORMATION CONTACT:** Todd Courtney, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2530, Silver Spring, MD 20993–0002, 301–796–6371, Todd.Courtney@fda.hhs.gov.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

Upon request, FDA has classified the external negative pressure airway aid 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.