must be tested and detailed protocols must be provided for each test:

(i) Bite test to ensure that the capsule can withstand extreme cases of biting.

(ii) pH resistance test to evaluate integrity of the capsule when exposed to a range of pH values.

(iii) Battery life test to demonstrate that the capsule's operating time is not constrained by the battery capacity.

(iv) Shelf-life testing to demonstrate that the device performs as intended at the proposed shelf-life date.

(v) Optical testing to evaluate fundamental image quality characteristics such as resolution, field of view, depth of field, distortion, signal-to-noise ratio, uniformity, and image artifacts. A test must be performed to evaluate the potential of scratches, caused by travelling through the gastrointestinal tract, on the transparent window of the capsule and their impact on the optical and color performance.

(vi) An optical safety analysis must be performed based on maximum (worst-case) light exposure to internal gastrointestinal mucosa, and covering ultraviolet, visible, and near-infrared ranges, as appropriate. A mitigation analysis must be provided.

(vii) A color performance test must be provided to compare the color differences between the input scene and output image.

(viii) The video viewer must clearly present the temporal or spatial relationship between any two frames as a real-time lapse or a travel distance. The video viewer must alert the user when the specific video interval is captured at a frame rate lower than the nominal one due to communication errors.

(ix) A performance test evaluating the latency caused by any adaptive algorithm such as adjustable frame rate must be provided.

(x) If the capsule includes a localization module, a localization performance test must be performed to verify the accuracy and precision of locating the capsule position within the colon.

(xi) A data transmission test must be performed to verify the robustness of the data transmission between the capsule and the recorder. Controlled signal attenuation should be included for simulating a non-ideal environment.

(xii) Software validation, verification, and hazards analysis must be provided.

(xiii) Electrical equipment safety, including thermal and mechanical safety and electromagnetic compatibility (EMC) testing must be performed. If the environments of intended use include locations outside of hospitals and clinics, appropriate higher immunity test levels must be used. Labeling must include appropriate EMC information.

(xiv) Information demonstrating immunity from wireless hazards.

(3) The clinical performance characteristics of the device for the detection of colon polyps must be established. Demonstration of the performance characteristics must include assessment of positive percent agreement and negative percent agreement compared to a clinically acceptable alternative structural imaging method.

(4) Clinician labeling must include:

(i) Specific instructions and the clinical and technical expertise needed for the safe use of the device.

(ii) A detailed summary of the clinical testing pertinent to use of the device, including the percentage of patients in which a polyp was correctly identified by capsule endoscopy, but also the percent of patients in which the capsule either missed or falsely identified a polyp with respect to the clinically acceptable alternative structural imaging method.

(iii) The colon cleansing procedure.

(iv) A detailed summary of the device technical parameters.

(v) A detailed summary of the device- and procedure-related complications pertinent to use of the device.

(vi) An expiration date/shelf life.

(5) Patient labeling must include:

(i) An explanation of the device and the mechanism of operation.

(ii) Patient preparation procedure.

(iii) A brief summary of the clinical study. The summary should not only include the percentage of patients in which a polyp was correctly identified by capsule endoscopy, but also the percent of patients in which the capsule either missed or falsely identified a polyp with respect to the clinically acceptable alternative structural imaging method.

(iv) A summary of the device- and procedure-related complications pertinent to use of the device.

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11173 Filed 5–15–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 880

[Docket No. FDA–2014–N–0438]

Medical Devices; General Hospital and Personal Use Devices; Classification of the Intravascular Administration Set, Automated Air Removal System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the intravascular administration set, automated air removal system 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 intravascular administration set, automated air removal system'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 June 16, 2014. The classification was effective on March 4, 2014.

FOR FURTHER INFORMATION CONTACT: Alan Stevens, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave. Bldg. 66, Rm. 2561, Silver Spring, MD 20993–0002, 301–796–6294.

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), 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.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112–144, July 9, 2012), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1), the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2). If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of ''low-moderate risk'' or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA will classify the device by written order within 120 days. This classification will be the initial classification of the device.

In accordance with section 513(f)(1) of the FD&C Act, FDA issued an order on October 23, 2008, classifying the AirPurge System into class III, because it was not substantially equivalent to a device that was introduced or delivered for introduction into interstate commerce for commercial distribution before May 28, 1976, or a device which was subsequently reclassified into class I or class II. On October 29, 2008, Anesthesia Safety Products, LLC submitted a request requesting classification of the AirPurge System under section 513(f)(2) of the FD&C Act. The manufacturer recommended that the device be classified into class II (Ref. 1).

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1) of the FD&C Act. FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on March 4, 2014, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 880.5445.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for an intravascular administration set, automated air removal system will need to comply with the special controls named in this final order. The device is assigned the generic name intravascular administration set, automated air removal system, and it is identified as a prescription device used to detect and automatically remove air from an intravascular administration set with minimal to no interruption in the flow of the intravascular fluid. The device may include an air identification mechanism, software, an air removal mechanism, tubing, apparatus to collect removed air, and safety control mechanisms to address hazardous situations.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks.

TABLE 1—IDENTIFIED RISKS AND MITIGATION MEASURES

Identified risk	Mitigation measures
Embolus	Hazard Argument. Software. Electromagnetic Compatibility. Human Factors. Labeling. Nonclinical Performance Testing.
Infusion Delivery Error	Hazard Argument. Software. Electromagnetic Compatibility. Human Factors. Labeling. Nonclinical Performance Testing.
Electric Shock	Hazard Argument. Electrical Safety. Electromagnetic Compatibility.
Adverse Tissue Reaction	Hazard Argument. Biocompatibility.
Infection	Sterilization. Shelf Life.

FDA believes that the following special controls, in combination with the general controls, address these risks to health and provide reasonable assurance of the safety and effectiveness:

1. Provide an argument demonstrating that all reasonably foreseeable hazards have been adequately addressed with respect to the persons for whose use the device is represented or intended and

the conditions of use for the device, which includes the following:

- Description of the device indications for use, design, and technology, use environments, and users in sufficient detail to determine that the device complies with all special controls.
- Demonstrate that controls are implemented to address device system hazards and their causes.
- Include a justification supporting the acceptability criteria for each hazard control.
- A traceability analysis demonstrating that all credible hazards have at least one corresponding control and that all controls have been verified and validated in the final device design.

2. Appropriate software verification, validation, and hazard analysis must be performed.

3. The device parts that directly or indirectly contact the patient must be demonstrated to be biocompatible.

4. Performance data must demonstrate the sterility of fluid path contacting components and the shelf life of these components.

5. The device must be designed and tested for electrical safety and electromagnetic compatibility (EMC).

6. Nonclinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

- Device system and component reliability testing must be conducted.
- Fluid ingress protection testing must be conducted.
- Testing of safety controls must be performed to demonstrate adequate mitigation of hazardous situations, including sensor failure, flow control failure, improper device position, device malfunction, infusion delivery error, and release of air to the patient.

7. A human factors validation study must demonstrate that use hazards are adequately addressed.

8. The labeling must include the following:

- The device's air identification and removal response time.
- The device's minimum air volume identification sensitivity.
- The minimum and maximum flow rates at which the device is capable of reliably detecting and removing air.
- Quantification of any fluid loss during device air removal operations as a function of flow rate.

Intravascular administration set, automated air removal systems are prescription devices restricted to patient use only upon the authorization of a practitioner licensed by law to administer or use the device (21 CFR 880.5445(a); see section 520(e) of the FD&C Act (21 U.S.C. 360j(e)) and 21 CFR 801.109 (*Prescription devices.*)). Prescription-use restrictions are a type of general controls as defined in section 513(a)(1)(A)(i) of the FD&C Act.

Section 510(m) of the FD&C Act provides that FDA may exempt a class II device from the premarket notification requirements under section 510(k) of the FD&C Act, if FDA determines that premarket notification is not necessary to provide reasonable assurance of the safety and effectiveness of the device. For this type of device, FDA has determined that premarket notification is necessary to provide reasonable assurance of the safety and effectiveness of the device. Therefore, this device type is not exempt from premarket notification requirements. Persons who intend to market this type of device must submit to FDA a premarket notification, prior to marketing the device, which contains information about the intravascular administration set, automated air removal system they intend to market.

II. Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling have been approved under OMB control number 0910–0485.

IV. Reference

The following reference has been placed on display in the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and is available electronically at *http://www.regulations.gov.*

1. K080644: De Novo Request per 513(f)(2) pursuant to the Agency's not substantially equivalent (NSE) determination, dated October 23, 2008, from Anesthesia Safety Products, LLC, dated October 29, 2008.

List of Subjects in 21 CFR Part 880

Medical devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 880 is amended as follows:

PART 880—GENERAL HOSPITAL AND PERSONAL USE DEVICES

■ 1. The authority citation for 21 CFR part 880 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 371.

■ 2. Add § 880.5445 to subpart F to read as follows:

§ 880.5445 Intravascular Administration Set, Automated Air Removal System.

(a) *Identification.* An intravascular administration set, automated air removal system, is a prescription device used to detect and automatically remove air from an intravascular administration set with minimal to no interruption in the flow of the intravascular fluid. The device may include an air identification mechanism, software, an air removal mechanism, tubing, apparatus to collect removed air, and safety control mechanisms to address hazardous situations.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) Provide an argument demonstrating that all reasonably foreseeable hazards have been adequately addressed with respect to the persons for whose use the device is represented or intended and the conditions of use for the device, which includes the following:

(i) Description of the device indications for use, design, and technology, use environments, and users in sufficient detail to determine that the device complies with all special controls.

(ii) Demonstrate that controls are implemented to address device system hazards and their causes.

(iii) Include a justification supporting the acceptability criteria for each hazard control.

(iv) A traceability analysis demonstrating that all credible hazards have at least one corresponding control and that all controls have been verified and validated in the final device design.

(2) Appropriate software verification, validation, and hazard analysis must be performed.

(3) The device parts that directly or indirectly contact the patient must be demonstrated to be biocompatible.

(4) Performance data must demonstrate the sterility of fluid path contacting components and the shelf life of these components.

(5) The device must be designed and tested for electrical safety and electromagnetic compatibility (EMC).

(6) Nonclinical performance testing data must demonstrate that the device performs as intended under anticipated conditions of use. The following performance characteristics must be tested:

(i) Device system and component reliability testing must be conducted.

(ii) Fluid ingress protection testing must be conducted.

(iii) Testing of safety controls must be performed to demonstrate adequate mitigation of hazardous situations, including sensor failure, flow control failure, improper device position, device malfunction, infusion delivery error, and release of air to the patient.

(7) A human factors validation study must demonstrate that use hazards are adequately addressed.

(8) The labeling must include the following:

(i) The device's air identification and removal response time.

(ii) The device's minimum air volume identification sensitivity.

(iii) The minimum and maximum flow rates at which the device is capable of reliably detecting and removing air.

(iv) Quantification of any fluid loss during device air removal operations as a function of flow rate.

Dated: May 9, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–11174 Filed 5–15–14; 8:45 am]

BILLING CODE 4160–01–P

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 79

[Docket ID: DOD–2011–OS–0124]

RIN 0790–AI81

Child Development Programs (CDPs)

AGENCY: Office of the Secretary, Department of Defense (DoD).

ACTION: Interim final rule.

SUMMARY: This interim final rule updates policy, responsibilities, and procedures for providing care to minor children birth through age 12 years of individuals who are eligible for care in DoD CDPs to include center-based care, family child care (FCC), school-age care (SAC), supplemental child care, and community based care; authorizes the publication of supporting guidance for the implementation of CDP policies and responsibilities, including child development training modules, program aids, and other management tools; and establishes the DoD Effectiveness Rating and Improvement System (ERIS).

DATES: *Effective date:* This rule is effective May 16, 2014.

Comment date: Comments must be received by July 15, 2014.

ADDRESSES: You may submit comments, identified by docket number and/or RIN number and title, by any of the following methods:

- *Federal Rulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments.
- *Mail:* Federal Docket Management System Office, 4800 Mark Center Drive, 2nd Floor, East Tower, Suite 02G09, Alexandria, VA 22350–3100.

Instructions: All submissions received must include the agency name and docket number or Regulatory Information Number (RIN) for this **Federal Register** document. The general policy for comments and other submissions from members of the public is to make these submissions available for public viewing on the Internet at *http://www.regulations.gov* as they are received without change, including any personal identifiers or contact information.

FOR FURTHER INFORMATION CONTACT: Eddy Mentzer, 571–372–0857.

SUPPLEMENTARY INFORMATION:

Justification for Interim Final Rule

This interim final rule provides overarching policy to the Military Departments in the execution of their roles in providing quality child development programs that ensure the safety and well-being of children in the DoD's care. A 2012 Secretary of Defense directed audit of criminal background check processes for all DoD Child and Youth Services personnel revealed the need areas for all applicable directives to be updated to ensure current and accurate policy is incorporated. The White House and Secretary of Defense directed a priority review of the management and oversight of child and youth programs in 2013. The review noted variation in Service-level approaches to oversight inspections including headquarters-level comprehensive inspections and installation-level fire, health, and safety inspections. The report recommended the OSD promulgate guidance to ensure standardization and clarity. Defense child development program staff and leadership have committed to the SECDEF and White House that they are committed to improving the consistency by which these services are delivered and to ensure the safety and well-being of children in our care. This interim final rule addresses these recommendations and creates a stronger environment of standardization across the services.

This interim final rule identifies the applicability of 32 CFR part 56, ''Nondiscrimination on the Basis of Handicap in Programs and Activities Assisted or conducted by the Department of Defense'' that implement section 504 of the Rehabilitation Act for federally conducted and federally assisted programs as they apply to children and youth with special needs. This interim final rule expands previous policy by (1) Requiring procedures for reviewing and making reasonable accommodation of children with special needs that do not fundamentally alter the nature of the program; (2) considering the needs of the child, the disability, and the environment of group care in child development facilities or home-based care, staffing needs and training requirements, and resources of the program; and (3) including Child Development Programs as part of the multi-disciplinary Inclusion Action Team that supports families of children with special needs.

This interim final rule extends child care benefits to same-sex spouse of Military Service members. At the direction of the President, the Department has conducted a careful and deliberative review of benefits currently provided. The Department has now identified family member and dependent benefits that we can lawfully provide to same-sex spouse and their children through changes in DoD policies and regulations. These benefits shall be extended to same-sex spouse and, where applicable, children of same-sex spouses.

Executive Summary

I. Purpose of the Regulatory Action

a. This interim final rule proposes to: (a) update policy, responsibilities, and procedures for providing care to minor children birth through age 12 years of individuals who are eligible for care in Department of Defense Child Development Programs (CDP) to include center-based care, family child care (FCC), school-age care (SAC),