

Location	Grantee	Amount
New York, NY .....	Cayuga Home for Children DBA Cayuga Centers .....	5,404,388
New York, NY .....	Cayuga Home for Children DBA Cayuga Centers .....	1,052,501
New York, NY .....	Catholic Guardian Services .....	1,664,514
Yonkers, NY .....	Leake and Watts Services, Inc .....	1,804,974
Yonkers, NY .....	Leake and Watts Services, Inc .....	473,826
U.S. Multi-City .....	Southwest Keys, Inc .....	10,257,820
U.S. Multi-City .....	Southwest Keys, Inc .....	1,330,080

ORR is continuously monitoring its capacity to provide post-release services to the unaccompanied alien children in HHS custody. ORR has specific requirements for the provision of services. Award recipients must have the infrastructure, licensing, experience, and appropriate level of trained staff to meet those requirements. The expansion of the existing post-release services program through this supplemental award is a key strategy for ORR to be prepared to meet its responsibility of safe and timely release of Unaccompanied Alien Children referred to its care by DHS and so that the US Border Patrol can continue its vital national security mission to prevent illegal migration, trafficking, and protect the borders of the United States.

*Statutory Authority:* This program is authorized by—

(A) Section 462 of the Homeland Security Act of 2002, which in March 2003, transferred responsibility for the care and custody of Unaccompanied Alien Children from the Commissioner of the former Immigration and Naturalization Service (INS) to the Director of ORR of the Department of Health and Human Services (HHS).

(B) The Flores Settlement Agreement, Case No. CV85–4544RJK (C.D. Cal. 1996), as well as the William Wilberforce Trafficking Victims Protection Reauthorization Act of 2008 (Pub. L. 110–457), which authorizes post release services under certain conditions to eligible children. All programs must comply with the Flores Settlement Agreement, Case No. CV85–4544–RJK (C.D. Cal. 1996), pertinent regulations and ORR policies and procedures.

**Elizabeth Leo,**

*Grants Policy Specialist, Division of Grants Policy, Office of Administration, Administration for Children and Families.*

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**BILLING CODE 4184–45–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2017–N–2901]

**Medical Devices; Validated Instructions for Use and Validation Data Requirements for Certain Reusable Medical Devices in Premarket Notifications**

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

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) has determined that it is necessary for manufacturers of certain reusable medical devices to include in their premarket notifications (510(k)s) instructions for use which have been validated and validation data regarding cleaning, disinfection, and sterilization, for which a substantial equivalence determination may be based. This notice includes a list of these reusable devices that will require validated instructions for use and validation data in their premarket notification. FDA is publishing this list in accordance with the requirements established by the 21st Century Cures Act. This action ensures that the premarket requirements for these device types are clear and predictable which facilitates more efficient review of these 510(k)s.

**DATES:** These actions are effective on August 8, 2017.

**FOR FURTHER INFORMATION CONTACT:**

Constance Soves, Food and Drug Administration, Center for Devices and Radiological Health, 10903 New Hampshire Ave., Bldg. 66, Rm. 1437, Silver Spring, MD 20993–0002, 301–796–6951.

**SUPPLEMENTARY INFORMATION:**

**I. Background**

The Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 301 *et seq.*), as amended, established a comprehensive system for the regulation of medical devices intended for human use. Section 513 of the FD&C Act (21 U.S.C. 360c) establishes three categories (classes) of devices, based on the

regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories of devices are class I (general controls), class II (special controls), and class III (premarket approval).

Devices introduced into interstate commerce for the first time on or after May 28, 1976 (generally referred to as post-amendments devices), are classified automatically by statute (section 513(f) of the FD&C Act) into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless FDA initiates one of the following procedures: (1) FDA reclassifies the device into class I or II; (2) FDA issues an order classifying the device into class I or II in accordance with section 513(f)(2) of the FD&C Act; or (3) FDA issues an order finding the device to be substantially equivalent, under section 513(i), to a predicate device that is already legally marketed. The Agency determines whether new devices are substantially equivalent to predicate devices through review of premarket notifications under section 510(k) of the FD&C Act (21 U.S.C. 360(k)). Section 510(k) of the FD&C Act and its implementing regulations, codified in Title 21 of the Code of Federal Regulations (21 CFR part 807, subpart E), require persons who intend to market a new device that does not require a premarket approval application under section 515 of the FD&C Act (21 U.S.C. 360e) to submit a premarket notification report (510(k)) containing information that allows FDA to determine whether the new device is “substantially equivalent” within the meaning of section 513(i) of the FD&C Act to a legally marketed device that does not require premarket approval.

On December 13, 2016, the President signed into law the 21st Century Cures Act (Pub. L. 114–255) (Ref. 1). Section 3059 of the 21st Century Cures Act, in part, amends section 510 of the FD&C Act to require FDA to publish in the **Federal Register** a notice identifying a list of reusable device types that must include validated instructions for use and validation data regarding cleaning, disinfection, and sterilization in their 510(k) submissions. This section also

provides that a 510(k) submission for a reusable device may not be substantially equivalent to a predicate device if the validated instructions for use and reprocessing validation data submitted as part of the 510(k) are inadequate.

Manufacturers of reusable medical devices are responsible for having labeling that bears adequate directions for use, including instructions on preparing a device for use under 21 CFR 801.5 and 801.109. However, in recent years, there have been significant changes in knowledge and technology involved in reprocessing reusable medical devices. Additionally, there has been an evolution towards more complex reusable medical device designs that are more difficult to clean, disinfect, and sterilize. FDA believes reusable devices must be designed for adequate reprocessing and safe reuse, with comprehensive and clear instructions for effective reprocessing procedures for use by health care facilities that reprocess these devices.

**II. Requirements for Validated Reprocessing Instructions and Reprocessing Validation Data for Reusable Medical Devices**

A reusable medical device is one intended for repeated use either on the

same or different patients, with appropriate cleaning and other reprocessing steps between uses. FDA has issued recommendations for reprocessing reusable devices in relevant documents, including the FDA guidance “Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling,” as information on the reprocessing validation methods necessary to be reported in a 510(k) submission (Ref. 2). FDA expects specific required validation data regarding cleaning, disinfection, and sterilization to be included in 510(k) submissions for certain reusable medical device types as outlined in tables 1 and 2 below.

FDA believes that a majority of manufacturers for the reusable devices listed below are already conducting validation of their reprocessing instructions because FDA already has provided recommendations for reprocessing validation in relevant FDA documents. Sponsors of new 510(k) notifications for reusable devices identified in the tables below must also include validation data regarding cleaning, disinfection, and sterilization, in addition to all the other required elements of a 510(k) identified in 21 CFR 807.87, starting on August 8, 2017.

**III. List of Certain Reusable Medical Devices and Design Features**

The 21st Century Cures Act (section 3059) requires the Agency to identify and publish a list of reusable device types that are required to include “instructions for use” and “validation data” regarding cleaning, disinfection, and sterilization in 510(k) notifications. Accordingly, FDA is publishing the list in table 1 that identifies those reusable medical devices that FDA has determined pose a greater likelihood of microbial transmission and represent a high risk of infection (subclinical or clinical) if they are not adequately reprocessed.

FDA believes arthroscopes, laparoscopic instruments, and electro-surgical instruments, and their respective accessories with specific design features, identified in table 2, may pose a challenge to adequate reprocessing. 510(k) notifications for such devices that incorporate any of the design features listed in table 2 must include validated reprocessing instructions and reprocessing validation data reports, and if such are determined to be inadequate, FDA will find the device not substantially equivalent.

**TABLE 1—REUSABLE DEVICES THAT REQUIRE VALIDATION DATA AND VALIDATED REPROCESSING INSTRUCTIONS BE INCLUDED IN 510(K) NOTIFICATION AND UPON WHICH FDA WILL DETERMINE SUBSTANTIAL EQUIVALENCE**

Device type	Product code	Device name	21 CFR section
Bronchoscopes (flexible or rigid) and accessories ....	EOQ	Bronchoscope (flexible or rigid) .....	21 CFR 874.4680
	PSV	Ultrasound bronchoscope .....	21 CFR 892.1550
	KTI	Bronchoscope accessory .....	21 CFR 874.4680
	BTG	Brush, biopsy, bronchoscope (non-rigid) .....	21 CFR 874.4680
	JEI	Claw, foreign body, bronchoscope (non-rigid) .....	21 CFR 874.4680
	JEL	Curette, biopsy, bronchoscope (rigid) .....	21 CFR 874.4680
	BST	Curette, biopsy, bronchoscope (non-rigid) .....	21 CFR 874.4680
	BWH	Forceps, biopsy, bronchoscope (non-rigid) .....	21 CFR 874.4680
	JEK	Forceps, biopsy, bronchoscope (rigid) .....	21 CFR 874.4680
	ENZ	Telescope, laryngeal-bronchial .....	21 CFR 874.4680
	KTR	Tube, aspirating, bronchoscope (rigid) .....	21 CFR 874.4680
JEJ	Tubing, Instrumentation, bronchoscope (brush sheath A/O aspirating).	21 CFR 874.4680	
Ear, Nose, and Throat (ENT) endoscopes and accessories.	EOX	Esophagoscope (flexible or rigid) .....	21 CFR 874.4710
	GCL	Esophagoscope, general & plastic surgery .....	21 CFR 876.1500
	FDW	Esophagoscope, rigid, gastro-urology .....	21 CFR 876.1500
	EOB	Nasopharyngoscope (flexible or rigid) .....	21 CFR 874.4760
	EQN	Laryngoscope, nasopharyngoscope .....	21 CFR 874.4760
	EWY	Mediastinoscope, surgical, and accessories .....	21 CFR 874.4720
Gastroenterology and Urology Endoscopes that have elevator channels (not including accessories). [e.g., duodenoscopes used for endoscopic retrograde cholangiopancreatography (ERCP)].	FDT	Duodenoscope and accessories, flexible/rigid .....	21 CFR 876.1500
	FAK	Panendoscope (gastroduodenoscope) .....	21 CFR 876.1500
	ODF	Mini endoscope, gastroenterology-urology .....	21 CFR 876.1500
Automated Reprocessors for Reusable Devices .....	FEB	Accessories, cleaning, for endoscopes .....	21 CFR 876.1500
	NZA	Accessories, germicide, cleaning, for endoscopes .....	21 CFR 876.1500
	OJJ	High level disinfection reprocessing instrument for ultrasonic transducers, mist.	21 CFR 892.1570
	NVE	Washer, cleaner, automated, endoscope .....	21 CFR 876.1500
	PSW	High level disinfection reprocessing instrument for ultrasonic transducers, liquid.	21 CFR 892.1570

TABLE 1—REUSABLE DEVICES THAT REQUIRE VALIDATION DATA AND VALIDATED REPROCESSING INSTRUCTIONS BE INCLUDED IN 510(k) NOTIFICATION AND UPON WHICH FDA WILL DETERMINE SUBSTANTIAL EQUIVALENCE—Continued

Device type	Product code	Device name	21 CFR section
Other Flexible Gastroenterology and Urology Endoscopes <sup>1</sup> (not including accessories).	FDF	Colonoscope and accessories, flexible/rigid .....	21 CFR 876.1500
	FBN	Choledochoscope and accessories, flexible/rigid .....	21 CFR 876.1500
	FDA	Enteroscope and accessories .....	21 CFR 876.1500
	FDS	Gastroscope and accessories, flexible/rigid .....	21 CFR 876.1500
	FAJ	Cystoscope and accessories, flexible/rigid .....	21 CFR 876.1500
	FGB	Ureterscope and accessories, flexible/rigid .....	21 CFR 876.1500
	ODG	Endoscopic ultrasound system, gastroenterology-urology	21 CFR 876.1500
Neurological endoscopes (not including accessories)	GWG	Endoscope, neurological .....	21 CFR 882.1480
Water-based heater-cooler systems for use in operating rooms.	DWC	Controller, Temperature, Cardiopulmonary Bypass .....	21 CFR 870.4250
	DWJ	System, Thermal Regulating .....	21 CFR 870.5900
System, Surgical, Computer Controlled Instrument ..	NAY	System, Surgical, Computer Controlled Instrument .....	21 CFR 876.1500
Arthroscopes and accessories <sup>2</sup> .....	HRX	Arthroscope .....	21 CFR 888.1100
Laparoscopic instruments and accessories <sup>2</sup> .....	GCJ	Laparoscope, general and plastic surgery .....	21 CFR 876.1500
Electrosurgical instruments and accessories <sup>2</sup> .....	GEI	Electrosurgical, cutting and coagulation and accessories	21 CFR 878.4400

<sup>1</sup> For endoscopes that fall under these product codes, 510(k) submissions must include reprocessing validation data for those endoscopes which are flexible.

<sup>2</sup> For devices that fall under these product codes, 510(k) submissions must include reprocessing validation data if the device possesses any of the design features listed in table 2 below.

TABLE 2—DESIGN FEATURES WHICH MAY POSE A CHALLENGE TO ADEQUATE REPROCESSING FOR ARTHROSCOPES, LAPAROSCOPIC INSTRUMENTS, AND ELECTROSURGICAL INSTRUMENTS, AND THEIR RESPECTIVE ACCESSORIES

Lumens (especially lumens of flexible design, multiple internal lumens, lumens that are not freely accessible, bifurcated lumens, lumens with internal surfaces that are not smooth, have internal ridges or sharp angles, or are too small to permit a brush to pass through).

Hinges, depressions, joints with gaps, overlapping or butted joints that result in acute angles, or ribbed or otherwise “roughened” surfaces (e.g., jaws).

Interior device channels.

Sleeves surrounding rods, blades, activators, inserters, etc.

Shafts within lumens.

Adjacent device surfaces between which debris can be forced or caught during use.

O-rings.

Stopcocks/Valves.

Crevices.

Fittings with very close tolerances.

Clamps that cannot be fully opened for cleaning.

Small internal parts (e.g., springs, magnets, etc.) that may become soiled.

Ridges, articulations or grooves.

Rough, irregular, discontinuous surfaces that can entrap or retain soil.

Capillary gaps.

Luer locks.

Porous materials (smooth surfaces are desirable, where possible).

Junctions between insulating sheaths and activating mechanisms (as in certain laparoscopic instruments).

Dead-ended chambers.

Internal movable device components such as multiple cables.

Device features that may entrap debris that can later become aerosolized (e.g., through application of power, etc.).

Devices with these or other design features that cannot be disassembled for reprocessing.

The Agency believes that these devices currently have the greatest risk of infection transmission and inadequate performance if not adequately reprocessed. In the future, the Agency may reevaluate and revise both tables as it deems necessary.

#### IV. Paperwork Reduction Act of 1995

This notice refers to previously approved collections of information found in 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 801 have been approved under

OMB control number 0910–0485 (medical device labeling); the collections of information in part 807, subpart E have been approved under OMB control number 0910–0120 (premarket notification); and the collections of information in 21 CFR part 820 have been approved under OMB control number 0910–0073 (quality system regulation).

#### V. References

The following references are on display in the Division of Dockets Management (see ADDRESSES) and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also

available electronically at <https://www.regulations.gov>. FDA has verified the Web site addresses, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

- 21st Century Cures Act, Public Law 114–255, available at <https://www.congress.gov/114/bills/hr34/BILLS-114hr34eah.pdf>.
- FDA’s Guidance, Reprocessing Medical Devices in Health Care Settings: Validation Methods and Labeling, March 2015, available at <http://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm253010.pdf>.

Dated: June 5, 2017.

**Anna K. Abram,**

*Deputy Commissioner for Policy, Planning, Legislation, and Analysis.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Health Resources and Services Administration

#### Agency Information Collection Activities: Proposed Collection: Public Comment Request; Information Collection Request Title: Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report OMB No. 0915-0172—Revision

**AGENCY:** Health Resources and Services Administration (HRSA), Department of Health and Human Services.

**ACTION:** Notice.

**SUMMARY:** In compliance with the requirement for opportunity for public comment on proposed data collection projects, HRSA announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

**DATES:** Comments on this ICR must be received no later than August 8, 2017.

**ADDRESSES:** Submit your comments to [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email [paperwork@hrsa.gov](mailto:paperwork@hrsa.gov) or call the HRSA Information Collection Clearance Officer at (301) 443-1984.

**SUPPLEMENTARY INFORMATION:** When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

*Information Collection Request Title:* Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report, OMB No. 0915-0172—Revision

*Abstract:* HRSA is updating the *Title V Maternal and Child Health Services*

*Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report.* This guidance is used annually by the 50 states and 9 jurisdictions (hereafter state) in applying for Block Grants under Title V of the Social Security Act and in preparing the required annual report. The updates proposed by HRSA's Maternal and Child Health Bureau (MCHB) for this edition of the guidance are intended to reinforce the role of the state in developing a Title V Maternal and Child Health (MCH) Action Plan that addresses its priority needs. These proposed updates further refine the reporting structure and vision that was outlined in the previous edition. As such, they are intended to enable a state to articulate its Title V program activities and leadership efforts for serving the MCH population. The proposed updates to the guidance are informed by comments received from state Title V MCH program leaders, national MCH leaders, and other MCH stakeholders.

Specific updates to this edition of the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report* include the following:

(1) The performance measure framework has been maintained, but a state has added flexibility to determine the best combination of National Performance Measures (NPMs) and State Performance Measures (SPMs) for addressing its identified MCH priority needs. States will address each priority need by either a NPM or SPM.

(2) The required minimum number of NPMs to be selected by a state has been reduced from eight to five. States will select at least one NPM in each of the five population health domains, specifically: (1) Women/Maternal Health; (2) Perinatal/Infant Health; (3) Child Health; (4) Children with Special Health Care Needs (CSHCN); and (5) Adolescent Health.

(3) A sixth and optional domain, Cross-cutting and Systems Building, has been added to replace the Cross-cutting/Life Course domain. The three NPMs that were formerly included in the Cross-cutting/Life Course domain (*i.e.*, NPM #13A/B, NPM #14 A/B and NPM #15) have been incorporated into the relevant population health domain(s). No NPMs are included in the Cross-cutting and Systems Building domain; however, a state may choose to include a SPM in this domain if relevant to its priority needs.

(4) The focus on evidence-based or evidence-informed strategies and measures (ESMs) continues, with an

enhanced definition of "evidence-base" provided. Clarifying instructions and state examples of ESMs have been added.

(5) Expectations around state Title V reporting on family/consumer partnership have been clarified. These expectations include enhanced discussion of specific program activities, the impact they have on all sectors of the MCH population, and their demonstrated value in improving MCH outcomes.

(6) The narrative reporting requirements around services for CSHCN have been strengthened to allow each state to identify and define the components of its system of services. States are also encouraged to reflect on the impact of these services within the context of the identified priority needs and the measures selected for the State Action Plan.

(7) Further anticipated reductions to state burden have been incorporated through more streamlined narrative reporting, particularly between the State Overview, Needs Assessment, and State Action Plan sections; clearer descriptions of expected content in each of the narrative sections; and refined instructions for completing the data reporting forms. Notable among these updates is the restructuring of the State Action Plan narrative discussion to allow a Title V program greater flexibility in describing its public health framework (*e.g.*, life course model), leadership and partnership roles, cross-cutting strategies, and the leveraging of resources.

The full extent of the anticipated burden reduction will be realized over time as states become more familiar with the updated instructions and reporting requirements. The burden estimates presented in the table below are based on previous burden estimates and consultation with a few states.

*Need and Proposed Use of the Information:* Each year, states are required to submit an application/annual report for Federal funds for their Title V MCH Services Block Grant to States Program to HRSA's MCHB (Section 505(a) of Title V of the Social Security Act). In addition, each state is required to conduct a comprehensive needs assessment every 5 years. The information and instructions for the preparation and submission of this application/annual report are contained in the *Title V Maternal and Child Health Services Block Grant to States Program: Guidance and Forms for the Title V Application/Annual Report*.

*Likely Respondents:* Per section 505(a) of Title V of the Social Security Act, the MCH Block Grant application/annual