REPORT TO CONGRESS

Annual Report
Premarket Approval of Pediatric Uses of Devices
FY 2017

Submitted Pursuant to
Section 515A of the Federal Food, Drug, and Cosmetic Act

U.S. Department of Health and Human Services

Food and Drug Administration

Executive Summary

Section 515A(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires the Food and Drug Administration (FDA or Agency) to submit an annual report to Congress that provides information concerning premarket approvals of devices labeled for pediatric use.[1] The report also includes information for premarket approvals where there is a pediatric subpopulation that suffers from the disease that the device is intended to treat, diagnose, or cure. This is FDA's eighth annual report pursuant to this requirement, and the Agency's first annual report since the amendments pursuant to the FDA Reauthorization Act of 2017 (FDARA).[2] The report provides information from FDA's Center for Devices and Radiological Health (CDRH) and reflects device approvals during fiscal year (FY) 2017 (October 1, 2016, through September 30, 2017).[3]

This report highlights the following information for final decisions in FY2017:[4]

- FDA approved 63 original and panel track supplement premarket approval applications (PMAs) and 3 humanitarian device exemption (HDE) applications—a total of 66 device approvals.

- Of the 66 total device approvals, FDA approved 16 PMAs and *2 HDEs indicated for use in a pediatric population or subpopulation.*[5]

- Of the remaining device approvals, 47 PMAs and 1 HDE were indicated for use in adults.[6] Of the 48, 42 of the approvals were determined to treat, diagnose, or cure a disease or condition which occurs similarly within a pediatric subpopulation.

- One PMA relied on data from adults to support a determination of a reasonable assurance of safety and effectiveness in pediatric patients.[7]

- *As required to report on by section 515A(a)(3)(H) of the FD&C Act, there were no devices for which FDA relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation. Additionally, there are no devices to report under section 515A(a)(3)(B) of the FD&C Act for which data available indicated that approved pediatric labeling*

[1] See FD&C Act 201(k) for the definition of "label"; see 21 CFR 1.3 for the definition of "labeling."
[2] Public Law 110-85.
[3] This 2017 FY annual report does not include statistical data on pediatric use of medical devices approved by the Center for Biologics Evaluation and Research (CBER).
[4] The final reporting requirements in italics are based on the new reporting requirements for pediatric information under section 502 of the FDA Reauthorization Act of 2017 (FDARA) (Public Law 115-52).
[5] Section 515A(c) defines "pediatric subpopulations" by reference to sections 520(m)(6)(E)(i) and 520(m)(6)(E)(ii) of the FD&C Act , as well as FDA's final rule to update 21 CFR 814.2(s) (79 FR 1740, January 10, 2014), which defines *pediatric patients* as persons aged 21 or younger at the time of their diagnosis or treatment. Information about these FY 2017 pediatric device approvals, including a device's review time and the pediatric population for which it was indicated at the time of initial approval, appears in this report within Appendix A
[6] As required to report on by section 515A(a)(3)(A) of the FD&C Act.
[7] As required to report on by section 515A(a)(3)(G) of the FD&C Act.

could confer a benefit to pediatric patients regarding devices used in pediatric patients but not labeled for such use.

- Out of the 66 approvals, two PMAs were exempted from user fees as the marketing application was indicated solely for a pediatric population.[8]

- The median time to review the 16 PMAs indicated for use in a pediatric population or subpopulation was 179 FDA days and 327.5 total elapsed review days.[9] The median time to review the 2 HDEs indicated for use in a pediatric population or subpopulation was 220.5 FDA days and 438.5 total elapsed review days.[10]

[8] HDE applications are exempt from user fees under section 738(a)(2)(B)(i) of the FD&C Act.
[9] FDA's Medical Device User Fee Amendments of 2012 (MDUFA III) commitment letter defined "FDA days" as calendar days when a submission is considered to be under review at the Agency for submissions that have been filed. Tracking of FDA days begins on the date of the receipt of the submission or the amendments to the submission that enables the submission to be filed. See https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm089734.pdf.
[10] *Ibid.*

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I. Introduction

As a science-based regulatory organization, it is the principal mission of the Center for Devices and Radiological Health (CDRH)[11] to ensure the safety, effectiveness, and quality of medical devices; accuracy of medical diagnostics; and safety of radiation-emitting products. Every day, the Food and Drug Administration (FDA) facilitates the development of innovative technologies and uses public health decision making to improve human lives. To foster innovation and promote timely access to safe, effective, and high-quality medical devices, CDRH has long been interested in a pediatric framework to explore the unique issues related to the performance of medical devices in the pediatric population.

The Food and Drug Administration Amendments Act of 2007 (FDAAA)[12] amended section 515A of the FD&C Act, "Pediatric Uses of Devices" (21 U.S.C. 360e-1). Section 515A(a) of the FD&C Act requires persons who submit certain medical device applications for which approval is sought to include, if readily available, a description of any pediatric subpopulations that suffer from the disease or condition that the device is intended to treat, diagnose, or cure, and the number of affected pediatric patients.

On August 18, 2017, the FDA Reauthorization Act of 2017 (FDARA)[13] added section 502 of FDARA, which amended section 515A(a)(3) of the FD&C Act to require additional information in FDA's annual report to Congress related to the number of devices approved with a pediatric indication.

Specifically, section 515A(a)(3) of the FD&C Act, as amended by FDARA, states that[14]:

> *Not later than 18 months after the date of the enactment of this section and annually thereafter, the Secretary shall submit to the Committee on Health, Education, Labor, and Pensions of the Senate and the Committee on Energy and Commerce of the House of Representatives a report that includes:*
>
> *(A) the number of devices approved in the year preceding the year in which the report in submitted, for which there is a pediatric subpopulation that suffers from the disease or condition the device is intended to treat, diagnose, or cure;*

[11] The mission of CDRH is to protect and promote the public health. We ensure that patients and providers have timely and continued access to safe, effective, and high-quality medical devices and safe radiation-emitting products. We provide consumers, patients, their caregivers, and providers with understandable and accessible science-based information about the products we oversee. We facilitate medical device innovation by advancing regulatory science; providing industry with predictable, consistent, transparent, and efficient regulatory pathways; and ensuring consumer confidence in devices marketed in the United States.

[12] Public Law 110-85.

[13] Public Law 115-52.

[14] The new requirements under FDARA are identified in bold font. The reporting data required under section 515A(a)(3)(B) of the FD&C Act is not available for the FY 2017 annual report because FDA did not have a mechanism in place to capture data for the Secretary to determine whether devices used in pediatric patients but not labeled for such use, if labeled for pediatric use, could confer a benefit to pediatric patients. FDA intends to include this data in our annual reports starting in the FY 2018 report.

(B) any information, based on a review of data available to the Secretary, regarding devices used in pediatric patients but not labeled for such use for which the Secretary determines that approved pediatric labeling could confer a benefit to pediatric patients;

(C) the number of pediatric devices that receive a humanitarian use exemption under section 520(m);

(D) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;

(E) the number of pediatric devices approved in the year preceding the year in which the report is submitted, exempted from a fee pursuant to section 738(a)(2)(B)(v);

(F) the review time for each device described in subparagraphs (A), (C), (D), and (E);

(G) the number of devices for which the Secretary relied on data with respect to adults to support a determination of a reasonable assurance of safety and effectiveness in pediatric patients; and

(H) the number of devices for which the Secretary relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation.

For the items described in this paragraph, such report shall disaggregate the number of devices by pediatric subpopulation. [Emphasis added.]

This is FDA's eighth report pursuant to section 515A(a)(3) of the FD&C Act since FDAAA's enactment. This FY2017 report includes information and accounting with respect to the approval of devices that are indicated for use in pediatric patients or that are intended to treat, diagnose, or cure diseases from which pediatric patients suffer, as required under section 515A of the FD&C Act for approvals made during FY2017.[15] Information submitted under section 515A(a) of the FD&C Act assisted in the development of this report. In addition, this report includes background information regarding section 515A of the FD&C Act and FDA's implementation of that provision.

II. Background

Section 515A of the FD&C Act and other provisions in FDAAA are intended to encourage the development of devices for use in pediatric patients. The House Report for FDAAA described the need for the legislation as follows:[16]

Pediatric medical devices are used to treat or diagnose diseases and conditions in patients from birth through age 21 years. Some products are designed specifically for children, while others are borrowed from adult applications or produced for more general use.

[15] The term "indications for use," as defined in 21 CFR 814.20(b)(3)(i), describes the disease or condition the device will diagnose, treat, prevent, cure or mitigate, including a description of the patient population for which the device is intended.

[16] House Committee on Energy and Commerce, "Food and Drug Administration Amendments Act of 2007," H. R.100-225, 110th Congress, 1st Session, on page 8.

Children have specific medical needs that must be considered when medical and surgical devices are prescribed. Devices that have not been studied for use in children may not accommodate the unique needs of children, such as allowing for expandable growth and accommodating their active lifestyles and differing metabolism.

Section 520(m)(6)(E)(i) of the FD&C Act defines pediatric patients, for medical device purposes, as age 21 years or younger at the time of diagnosis or treatment (i.e., inclusive of the patient's 21st year of life). Additionally, pediatric subpopulations are specified by section 520(m)(6)(E)(ii) of the FD&C Act (and adopted by reference in section 515A(c) of the FD&C Act) to mean one of the following populations: neonates, infants, children, and adolescents.

Age ranges for these pediatric subpopulations are:

- Neonates (birth until 1 month of age);[17]
- Infants (greater than 1 month until 2 years of age);
- Children (greater than 2 years until 12 years of age); and
- Adolescents (greater than 12 years through 21 years of age [i.e., up to but not including the 22nd birthday])

On January 10, 2014, FDA issued a final rule in the *Federal Register* (79 FR 1735) amending the regulations to require inclusion of information relating to pediatric subpopulations that suffer from the disease or condition that a device is intended to treat, diagnose, or cure, and the number of affected pediatric patients.[18] These requirements are mandated under section 515A of the FD&C Act, as amended by FDAAA and FDARA.

On March 24, 2014, FDA issued the final guidance entitled "Premarket Assessment of Pediatric Medical Devices," which provides information for applicants regarding the pediatric information requirement in a question-and-answer format.[19] On May 1, 2014, FDA issued a final guidance document entitled "Providing Information about Pediatric Uses of Medical Devices."[20] On June 21, 2016, FDA also issued a final guidance document entitled "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices" (Pediatric Extrapolation Guidance).[21] The Pediatric Extrapolation Guidance explains the circumstances in which it may be appropriate to extrapolate existing medical device data to support pediatric device indications in PMAs, HDEs, and De Novo requests. This guidance also describes FDA's approach for

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[17] Section 520(m)(6)(E) of the FD&C Act.

[18] Pediatric Uses of Devices; Requirement for Submission of Information on Pediatric Subpopulations That Suffer From a Disease or Condition That a Device Is Intended To Treat, Diagnose, or Cure, Final Rule, January 10, 2014 (79 FR 1735 at 1735-1741). https://www.federalregister.gov/documents/2014/01/10/2014-00267/medical-devices-pediatric-uses-of-devices-requirement-for-submission-of-information-on-pediatric

[19] FDA guidance on "Premarket Assessment of Pediatric Medical Devices," available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM089742.pdf.

[20] FDA guidance on "Providing Information about Pediatric Uses of Medical Devices," available at https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM339465.pdf

[21] FDA guidance on "Leveraging Existing Clinical Data for Extrapolation to Pediatric Uses of Medical Devices," available at https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm444591.pdf.

determining whether extrapolation may be appropriate and the factors that should be considered within a statistical model for extrapolation.

III. Summary of Information Required by Section 515A(a)(3) of FD&C Act

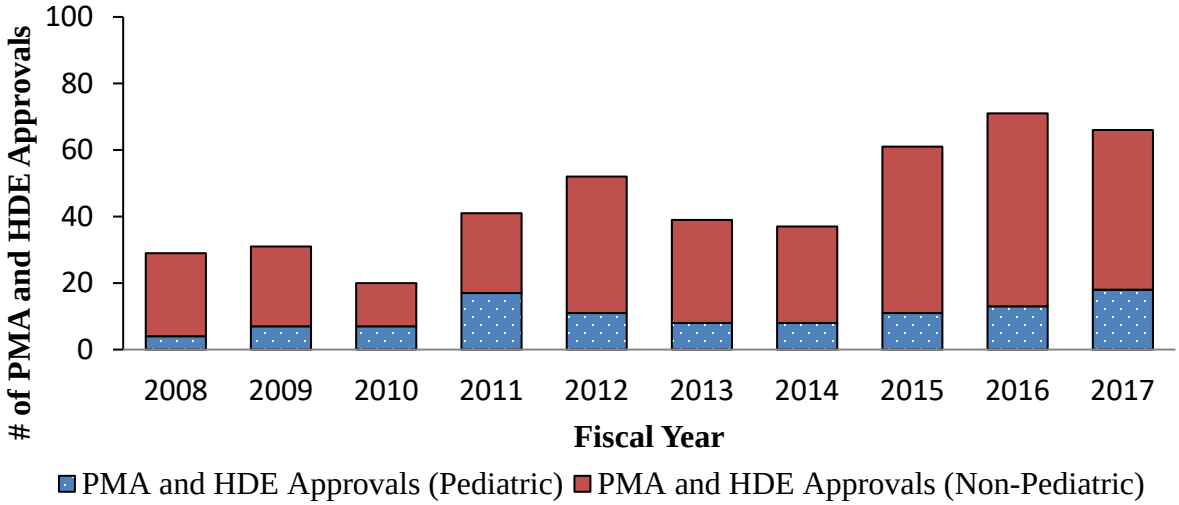
In FY2017, there were 66 total device approvals. However, only 18 approvals (27%), 16 PMAs and 2 HDEs, had an indication for use in a pediatric population or subpopulation. Among the 16 PMAs indicated for use in a pediatric population or subpopulation, there was a median of 179 FDA review days and 327.5 total elapsed review days. Also, for the 2 HDEs indicated for use in a pediatric population or subpopulation, the median time to review was 220.5 FDA days and 438.5 total elapsed review days.

As required to report on under section 515A(a)(3)(G) of the FD&C Act, in FY2017, one PMA relied on data from adults to support a determination of a reasonable assurance of safety and effectiveness in pediatric patients. However, there were no devices for which the FDA relied on data from one pediatric subpopulation to support a determination of a reasonable assurance of safety and effectiveness in another pediatric subpopulation, as required to report on under section 515A(a)(3)(H) of the FD&C Act. Additionally, there were no devices to report under section 515A(a)(3)(B) of the FD&C Act for which data available indicated that approved pediatric labeling could confer a benefit to pediatric patients regarding devices used in pediatric patients but not labeled for such use.

In the past decade (FY2008-FY2017), a total of 447 PMAs and HDEs have been approved, with an average of around 45 device approvals per year. Of those device approvals, a total of 96[22] were approved with an indication for use in a pediatric population or subpopulation at the initial time of marketing authorization. Since FY2008, there has been a relatively steady increase in PMA and HDE approvals (non-pediatric) (Figure 1A and Appendix B – Table 1). Since the first pediatric report (FY2008), the greatest number of total PMA or HDE approvals was in FY2016 (71) and the lowest number of PMA or HDE approvals was in FY2010 (20).

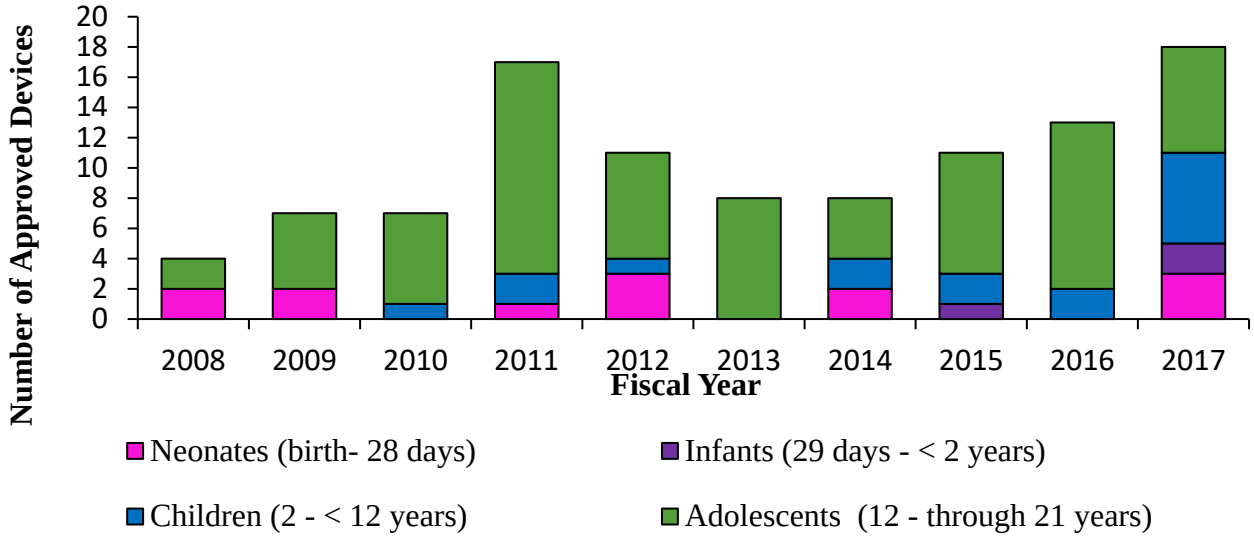
[22] Number obtained by totaling PMA and HDE approvals indicated for pediatric patients from FY 2008 - 2017; see Appendix B, Table 1.

Figure 1A. PMA and HDE approvals for non-pediatric (red) and with pediatric (blue) indications from FY2008-FY2017.



Based upon a retrospective reanalysis of prior PMA and HDE approvals from FY2008 through FY2017, 38 out of the total 58 (66%) PMA and HDE approvals were indicated for the pediatric subpopulation of adolescents (Figure 1B and Appendix B – Table 2). Meanwhile, only about 9 percent, 5 out of the total 58 PMA and HDE approvals in pediatrics, were indicated for use in neonates and infants.

Figure 1B. PMA and HDE approvals indicated for pediatric subpopulations by age from FY 2008 - 2017. PMA and HDE approvals were categorized by the youngest age for which there was an indication for use.



Appendix A includes a detailed summary of each of the FY2017 PMA and HDE approvals which were indicated for use in a pediatric population or pediatric subpopulation.

Since FY2008, the largest number of PMA and HDE approvals for an indication which included a pediatric population or subpopulation was in FY2017 (18). The largest percentage of PMA and HDE approvals for an indication that included a pediatric population or subpopulation was in FY2011 (41.5%) (Figure 2A).[23] On average for the last 10 years, only 24 percent of the total PMA and HDE approvals in each fiscal year have an indication which includes a pediatric population or subpopulation. The percentage of pediatric indications increased between FY2008 and FY2011, with the highest percentage of approvals in 2011 at 41.5 percent. Starting in FY2012, the percentage of PMA and HDE approvals with pediatric indications declined to 21 percent, only rising again to 27 percent in FY2017. Linear regressions were fit to the absolute numbers of PMA and HDE approvals (Figure 2B). The number of approved PMAs and HDEs for adults increased at a rate of 3.8 each year, while the number of approved PMAs and HDEs with pediatric indications increased at only a rate of 1 per year.

Figure 2A. Percentage of total PMA and HDE approvals with an indication for pediatric patients.

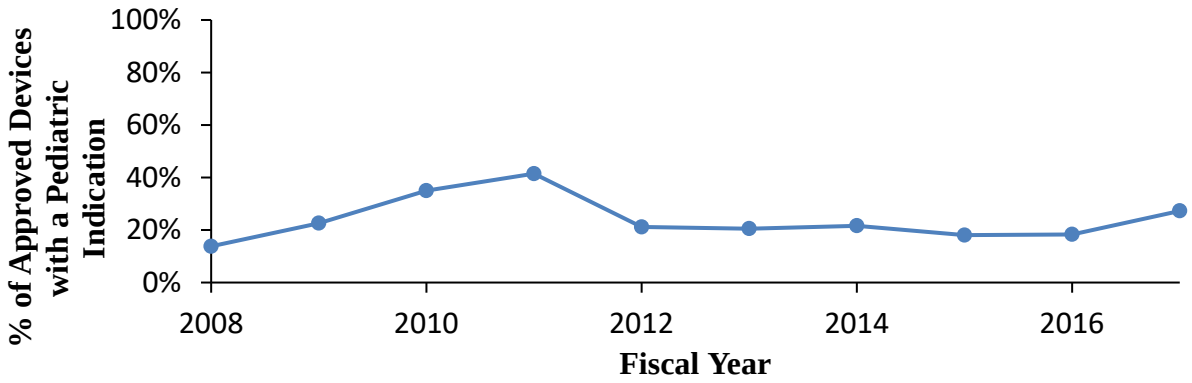
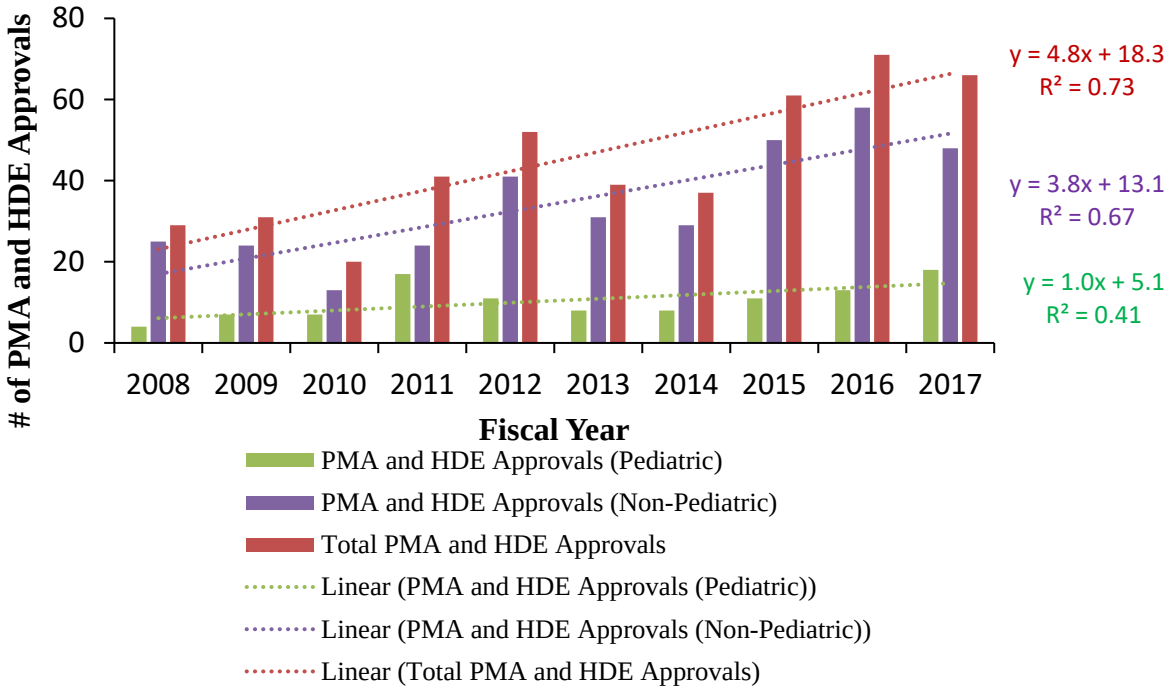


Figure 2B. Linear regression fits to pediatric, non-pediatric, and total number of PMA and HDE approvals ($p<0.05$ for each linear fit).

[23] Data cleaning was conducted for prior years that indicated inconsistencies with accounting identified in prior reports. This figure reflects the most up-to-date numbers. The methodology used for data cleaning included the following: 1) reexamination of the indications for use as stated in the Summary of Safety and Effectiveness Data (SSED) or the Summary of Safety and Probable Benefit (SSPB); and 2) determination if years of age in number form and/or the word "pediatrics" was explicitly identified in the SSED or SSPB.



IV. Conclusion

Since FY2008, FDA has submitted an annual report to Congress providing information concerning premarket approvals of devices indicated for pediatric use. This is FDA's eighth report pursuant to section 515A(a)(3) of the FD&C Act since FDAAA's enactment, as amended by FDARA.

This report includes information on medical device approvals in FY2017, which includes devices that were indicated for use in pediatric populations or subpopulations. Based on the information summarized in this report, there have been limited changes in PMA or HDE approvals indicated for use in pediatric populations or subpopulations over the last decade. Since the passage of FDAAA, the number of devices approved for pediatric subpopulations has increased; however, the percentage of devices indicated for use in the pediatric population out of the total devices approved each year has remained relatively constant (Appendix B, Table 1).

FDA is committed to supporting the development and availability of safe and effective medical devices for use in pediatric populations. Our current initiatives in the development of pediatric medical devices include:[24]

- Protecting children who participate in clinical trials

[24] More information is available at https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm596777.htm.

- Increasing the number of medical devices with labeling for pediatric patients by incorporating known information about device effects in other populations to support pediatric indications.
- Increasing post-market surveillance of pediatric medical devices.
- Recruiting pediatric experts for FDA advisory panels whenever there is a reasonable likelihood that the device under discussion will be used for children.
- Collecting data on the unmet needs for pediatric medical devices and the barriers to the development of new pediatric devices.

As required under section 502(d) of FDARA, FDA held a public meeting on pediatric medical device development on August 13-14, 2018. The public meeting was held to identify opportunities to support development and innovation of medical devices designed and labeled for children. [25] A subsequent annual report will provide additional details associated with the congressional goals identified in FDARA that are related to this public meeting.

[25] As directly outlined in FDARA, the meeting included consideration of ways to: (1) improve research infrastructure and research networks to facilitate the conduct of clinical studies of devices for pediatric populations that would result in the approval (or clearance) and labeling of medical devices for such populations; (2) appropriately use extrapolation under section 515A(b) of the FD&C Act; (3) enhance the appropriate use of postmarket registries and data to increase pediatric medical device labeling; (4) increase FDA assistance to medical device manufacturers in developing devices for pediatric populations that are approved (or cleared) and labeled for their use; and (5) identify current barriers to pediatric device development and incentives to address such barriers. More information about the public meeting is available at https://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/ucm596777.htm.

Appendix A[26]

FY 2017 Device PMA and HDE Approvals Indicated for Use in Pediatric Patients with Review Times

FY 2017
PMA Device Information

AMPLATZER™ PFO Occluder

The AMPLATZER PFO Occluder is a self-expanding, double disc device made from a Nitinol wire mesh. The wire mesh is formed into a device containing two discs linked together by a short connecting waist. The waist allows each disc to articulate in relationship to the defect and conform to the septal wall. In order to increase its closing ability, the discs contain thin polyester fabric. The polyester fabric is securely sewn to each disc by a polyester thread. The device is delivered percutaneously via a delivery cable attached to the end screw at the proximal disc of the device. This end screw allows the device to be attached to a delivery cable and loaded into a transcatheter delivery system for percutaneous implantation as well as for recapture if required.

Manufacturer	St. Jude Medical, INC.
Number	P120021
Filing Date	11/30/2012
Approval Date	10/28/2016
Approved, Indicated Pediatric Subpopulation:	18
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	700
Total Review Days	1428

iDesign Advanced WaveScan Studio System STAR S4 IR Excimer Laser System

The *iDesign Advanced WaveScan Studio* System incorporates wavefront aberrometry, auto-refractometry, corneal topography, keratometry, and pupillometry. The System measures the refractive error and wavefront aberrations of the human eye using a high-definition Hartmann-Shackwavefront sensor. The measurements can be used to determine regular (sphero-cylindrical) refractive errors and irregularities (aberrations) that may cause decreased or blurry vision in the human eye.

Manufacturer	AMO Manufacturing USA, LLC.
Number	P930016/S045
Filing Date	06/02/2015
Approval Date	11/14/2016
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	180
Total Review Days	531

[26] Additional information pertaining to these devices can be found in the SSED or the SSPB by searching the PMA or HDE number, respectively. The PMA and HDE approvals are listed in chronological order from earliest approval date.

WaveLight® EX500 Excimer Laser System, ALLEGRETTO WAVE® EYE-Q Excimer Laser System

ALLEGRETTO WAVE EYE-Q Excimer Laser System
The EYE-Q is a scanning-spot Excimer laser system used in refractive surgery for the treatment of refractive errors of the human eye. The system consists of a compact excimer laser with high pulse frequency, a galvanometer scanner for positioning the laser spot, and a fast eye-tracker for determining eye position and laser beam direction. The integrated eye-tracker offers automatic centration of the ablation and tracking of eye movements. The specially shaped profile of the treatment laser beam and the small spot size ensure the required accuracy to achieve the desired contour of the treated corneal surface.
The WaveNet™ Planning Software (WPS) allows the physician to plan treatments on a portable notebook computer outside the surgical area in the same way as if directly on the device. The software is made available to the surgeon on a standard DVD-ROM and can be used with any notebook computer meeting the specified hardware requirements.
WaveLight EX500 Laser System
EX500 uses the same scanning technique for positioning the laser spot and same eyetracker to determine the eye position and laser mean direction as in EYE-Q. Similarly, the WaveNet Planning Software is used for planning treatment. As for treatment parameter, EX500 provides the same wavelength, fluence, beam diameter, and ablation zone as EYE-Q.

Manufacturer	Alcon Laboratories, Inc.
Number	P020050/S023
Filing Date	07/20/2015
Approval Date	11/21/2016
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	292
Total Review Days	490

OneTouch Vibe™ Plus System

The OneTouch Vibe™ Plus System (“Vibe System”) consists of the Animas® Vibe® Insulin Pump (“The Pump”) and Dexcom G5® CGM System. The Vibe® System includes an insulin infusion pump, designed to communicate via BLE technology with the Dexcom CGM transmitter to display CGM information in addition to infusion pump data, Animas 2.0 mL cartridge, infusion set, and one lithium battery. The insulin infusion pump delivers insulin through the OneTouch™ Infusion Set for continuous subcutaneous insulin infusion for the management of insulin-requiring diabetes. The Dexcom G5® CGM System sensor (“the Sensor”) provides continuous measurements of glucose in the tissue over the range of 40 to 400 mg/dL for up to seven days of use measuring and displaying glucose values and trends for patients with diabetes mellitus on the pump. The Vibe® System provides glucose trends, alerts and a low glucose alarm.

Manufacturer	Animas Corporation
Number	P130007/S016
Filing Date	06/07/2016
Approval Date	12/16/2016
Approved, Indicated Pediatric Subpopulation:	2 and older

Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	165
Total Review Days	192

Dexcom G5 Mobile Continuous Glucose Monitoring System

The Dexcom G5 Mobile Continuous Glucose Monitoring System (Dexcom G5), as approved in P120005/S033, consists of a sensor, transmitter, receiver, and mobile application. The sensor is a small, flexible, coated metal filament which is inserted into subcutaneous tissue where it generates an electrical current proportional to the local glucose concentration. The sensor is held in place by an adhesive patch. The transmitter is connected to the sensor and is worn on the body. It samples the electrical current produced by the sensor and converts these measurements into glucose readings using an onboard algorithm. The transmitter uses Bluetooth Low Energy (BLE) for two-way communication with both the Dexcom G5 receiver and a BLE-enabled Apple iOS device in order to send glucose data and receive blood glucose calibration and other user inputs from these two display devices. The receiver displays the current glucose reading (which is updated every 5 minutes) and glucose trends (for up to the previous 24 hours) from the transmitter. The receiver alerts the user when glucose levels are outside of a target zone, when it is time to enter a blood glucose value to calibrate the system, and for other important system conditions. Blood glucose values for calibration are required at least twice per day and are obtained by measuring fingertip capillary blood using a conventional blood glucose monitoring device. The mobile application provides an alternative user interface to the receiver for users with a compatible Apple iOS device. It provides similar glucose display, alert, and calibration functionality to the receiver and additionally provides connectivity to the Dexcom Share service which allows Dexcom G5 users to share glucose information in real-time with up to five selected individuals.

Manufacturer	Dexcom, INC.
Number	P120005/S041
Filing Date	09/25/2015
Approval Date	12/20/2016
Approved, Indicated Pediatric Subpopulation:	2 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	299
Total Review Days	452

Elecsys HBsAg II
Elecsys HBsAg Confirmatory Test
PreciControl HBsAg II

Elecsys HBsAg II
The Elecsys HBsAg II is a qualitative serologic, two- incubation step assay using a sandwich test format and a total assay time of 18 minutes that enables detection of HBsAg. The assay is performed on the cobas e 601 immunoassay analyzer.

Elecsys HBsAg Confirmatory Test
Elecsys HBsAg Confirmatory Test is an independent neutralization test used for further investigation of the repeatedly reactive samples. Samples confirmed by neutralization with human anti-HBs are regarded as positive for HBsAg.

PreciControl HBsAg II
The PreciControl HBsAg II is used for quality control testing of the Elecsys HBsAg II test.

Manufacturer	Roche Diagnostics, INC.
Number	P160019
Filing Date	07/01/2016
Approval Date	12/23/2016
Approved, Indicated Pediatric Subpopulation:	2 to 21
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	175
Total Review Days	175

HeartSine samaritan® PAD 350P (SAM 350P), HeartSine samaritan® PAD 360P (SAM 360P), and HeartSine samaritan® PAD 450P (SAM 450P)

A. samaritan® PAD Models SAM 350P, SAM 360P and SAM 450P Defibrillators
The samaritan® PAD Models SAM 350P, SAM 360P, and SAM 450P are portable, battery operated, prescription Automated External Defibrillators (AEDs) designed to treat victims of cardiac arrest. The devices are Public Access Defibrillators (PAD) intended for use by minimally trained users. The user interface incorporates voice and text/icon prompts to guide the user in the use of the device. The devices also incorporate an audible metronome to guide the user as to the correct rate at which chest compressions should be administered in accordance with current American Heart Association (AHA) resuscitation guidelines.

B. Pad-Pak™ (Electrode and Battery Pack)
The Pad-Pak™ is a combined, single use, battery and electrode unit. The electrodes are two (2) non-sterile, single-use, self-adhesive, conductive gelled defibrillation electrodes. All three (3) AED devices are compatible with all 3 Pad-Pak versions. The three (3) versions of the Pad-Pak™ are: (1) a standard adult version (Pad-Pak™-01), (2) a pediatric version (Pediatric-Pak™-02), and (3) a standard adult version meeting US Federal Aviation Administration standards for use on commercial aircraft (Pad-Pak™-07). The pediatric version is for use on patients between the ages of 1 and 8 years or less than 55 lbs. (25 kg). When inserted into the AED, the Pediatric Pad-Pak enables delivery of 50 Joule non-escalating shocks in accordance with the AHA Resuscitation guidelines.

C. Saver EVO® Software
The Saver EVO® software is an optional accessory for use with the SAM 350P, SAM 360P, and SAM 450P defibrillators. The Saver EVO® software can be used to view and/or download the patient's recorded ECG, adjust audio and visual device outputs, run diagnostic tests on the devices, and check for upgrades to the latest Saver EVO® software version. All other settings such as energy protocol, CPR duration, and the metronome rate are not user configurable.

Manufacturer	HeartSine Technologies LLC.
Number	P160008
Filing Date	03/21/2016
Approval Date	01/12/2017
Approved, Indicated Pediatric Subpopulation:	Greater than 8 when used with the adult Pad-Pak, Between 1 and 8 when used with Pediatric-Pak
Exempt from User Fees because intended solely for pediatric use?	No

FDA Review Days	180
Total Review Days	297

PROPEL® Contour Sinus Implant

The PROPEL Contour sinus implant is a bioabsorbable implant designed to maintain patency of the peripheral sinus ostia. The PROPEL Contour sinus implant is manufactured from a synthetic bioabsorbable copolymer, poly (L-lactide-co-glycolide) (PLG). The implant contains mometasone furoate (active ingredient), a synthetic corticosteroid with anti-inflammatory activity. Mometasone furoate is a white to off-white powder. The chemical name is 9α,21-dichloro-11β,17α-dihydroxy-16α-methylpregna-1,4-diene-3,20-dione17-(2-furoate), with the empirical formula $C_{27}H_{30}Cl_2O_6$, and a molecular weight of 521.43 g/mol. Mometasone furoate is a hydrophobic drug that is practically insoluble in water. Mometasone furoate is stable under aqueous, acidic and oxidative conditions. MF can degrade under extreme basic, thermal and photolytic conditions. The chemical structure is shown. The drug is embedded in a bioabsorbable polymer matrix containing poly-(DL-lactide-co-glycolide) and polyethylene glycol (inactive ingredients) which provides for gradual release of the drug.

Manufacturer	Intersect ENT
Number	P100044/S023
Filing Date	08/01/2016
Approval Date	02/23/2017
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	180
Total Review Days	206

Melody™ Transcatheter Pulmonary Valve (TPV) and Ensemble™ Transcatheter Valve Delivery System

The Melody TPV system consists of two (2) components: the Melody TPV and the Ensemble/Ensemble II Delivery System (DS).

Melody TPV
The Melody TPV consists of a bovine jugular vein (BJV) with a native valve, sutured into a platinum iridium frame (Figure 1). It is available in two (2) sizes: a 16 mm BJV which can be expanded to 20 mm and an 18 mm BJV which can be expanded to 22 mm. Both the 16 mm and 18 mm sizes of the Melody TPV utilize the same platinum iridium frame, which is expanded at implantation to the respective size.

Ensemble DS
The Ensemble DS is designed to deliver a mounted Melody TPV via venous access to a failing RVOT conduit or pulmonary bioprosthesis previously implanted for the repair of congenital pathologies (Figure 2). It consists of a balloon-in-balloon catheter with a retractable sheath, and has a 22 Fr crossing profile. Both balloons are made of nylon. The delivery system comes in outer balloon sizes of 18, 20, and 22 mm (NU1018, NU1020, and NU1022, respectively). It is compatible with a 0.035-inch guidewire.

Ensemble II DS
The Ensemble II DS is a design iteration of the Ensemble DS, with the addition of radiopaque marker bands to aid in visibility of balloon location under fluoroscopy and some material changes. It also comes in outer balloon sizes of 18, 20, and 22 mm (ENS1018, ENS1020, and ENS1022, respectively).

Manufacturer	Medtronic, Inc.
Number	P140017/S005
Filing Date	09/01/2016
Approval Date	02/24/2017
Approved, Indicated Pediatric Subpopulation:	Pediatric patients[27]
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	176
Total Review Days	176

AED Plus
Fully Automatic AED Plus

The ZOLL AED Plus and Fully Automatic AED Plus devices are lightweight, portable, battery-powered automated external defibrillators that uses voice prompts and visual icons to guide a user through a resuscitation sequence that may include defibrillation and/or cardiopulmonary resuscitation (CPR). The devices utilize the ZOLL Rectilinear Bi-Phasic defibrillation waveform, and operate in either adult or pediatric mode. The AED Plus and Fully Automatic AED Plus support both adult and pediatric defibrillation electrode pads, and automatically adjusts the defibrillation energy based on the type of electrode pads connected to it. The devices are designed to be used by trained responders for the treatment of cardiac arrest. The AED Plus and the Fully Automatic AED Plus are the same in physical design and visually in the labeling of the top cover, however, the Fully Automatic AED Plus is further labeled as "Automatic" near the on/off switch of that device.

Manufacturer	Zoll Medical Corporation
Number	P160015
Filing Date	06/02/2016
Approval Date	5/26/2017
Approved, Indicated Pediatric Subpopulation:	>2yrs
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	178
Total Review Days	358

EXCOR® Pediatric Ventricular Assist Device

EXCOR Pediatric is an extracorporeal, pneumatically driven, pulsatile ventricular assist device. It is designed to support the right and/or left ventricle when the natural heart is unable to maintain normal blood flows, and/or pressures even with help of drug therapy and intra-aortic balloon counterpulsation. The device is designed for mid- to long-term mechanical support.

Manufacturer	Berlin Heart Inc.
Number	P160035
Filing Date	08/23/2016
Approval Date	06/06/2017
Approved, Indicated Pediatric Subpopulation:	Pediatric[28]
Exempt from User Fees because intended solely for pediatric use?	Yes
FDA Review Days	180

[27] Indication for use does not specify pediatric subpopulation.
[28] Indication for use does not specify pediatric subpopulation.

Total Review Days	287

VNS Therapy System

The VNS Therapy System used for vagus nerve stimulation (VNS), consists of the implantable VNS Therapy Pulse Generator, the VNS Therapy Lead and the external programming system used to change stimulation settings. The lead and the pulse generator make up the implantable portion of the VNS Therapy System. Electrical signals are transmitted from the pulse generator to the vagus nerve by the lead. The software allows a physician to identify, read and change device settings. The pulse generator is surgically placed in the left chest. The lead is then connected to the pulse generator and attached to the left vagus nerve. Patients are provided with magnets that, by placing the magnet over the implanted pulse generator can deactivate (turn OFF) programmed stimulation. Programmed stimulation resumes when the magnet is removed.

Manufacturer	VNS Therapy System
Number	P970003/S207
Filing Date	11/17/2016
Approval Date	06/23/2017
Approved, Indicated Pediatric Subpopulation:	4 and older
Exempt from User Fees because intended solely for pediatric use?	Yes
FDA Review Days	178
Total Review Days	218

iDESIGN advanced WaveScan Studio System and STAR S4 IR Excimer Laser System

The *iDESIGN® AWS Studio* System incorporates wavefront aberrometry, auto-refractometry, corneal topography, keratometry, and pupillometry. The System measures the refractive error and wavefront aberrations of the human eye using a high-definition Hartmann-Shackwavefront sensor. The measurements can be used to determine regular (sphero-cylindrical) refractive errors and irregularities (aberrations) that may cause decreased or blurry vision in the human eye.

Manufacturer	AMO Manufacturing USA, LLC.
Number	P930016/S048
Filing Date	12/02/2016
Approval Date	06/30/2017
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	178
Total Review Days	210

t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM

The t:slim X2 Insulin Pump with Dexcom G5 Mobile CGM ("t:slim X2 System") consists of the t:slim X2 Insulin Pump (k162080) paired with the Dexcom G5 Mobile Sensor and Transmitter (P120005/S041 and P120005/S049). The Dexcom G5 Mobile Sensor and Transmitter work together to wirelessly send glucose readings to the t:slim X2 Insulin Pump.
The t:slim X2 Insulin Pump has been modified from the approved t:slim G4 Insulin Pump (P140015) to include the functionality of the approved Dexcom G5 Receiver (i.e., incorporate a Bluetooth Low Energy (BLE) radio). Additionally, the t:slim X2 System includes a secondary supplier to the pump motor/gearbox

assembly (approved in P140015/S016) and a different cartridge/infusion set connector (approved in P140015/S017) compared to the t:slim G4 System. Changes to the pump software have been made to accommodate the new BLE radio and changes to the Tandem Device Updater (TDU) software (k160482, k162080), which allows remote updates of users' pumps, have been made to allow for compatibility with the G5 System hardware. No modifications have been made to the approved Dexcom G5 Sensor and Transmitter.

Manufacturer	Tandem Diabetes Care, Inc.
Number	P140015/S020
Filing Date	03/01/2017
Approval Date	08/25/2017
Approved, Indicated Pediatric Subpopulation:	6 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	177
Total Review Days	177

ZEUS ELISA Parvovirus B19 IgM Test System

The ZEUS ELISA Parvovirus B19 IgM Test System is designed to detect IgM class antibodies to parvovirus B19 in human sera. The test uses an indirect, enzyme-linked immunosorbent assay (ELISA) format and includes the following key components; ELISA microwell plate, Sample Diluent, Conjugate, Substrat Solution, and Control/Calibrator. The microwell strips are coated with recombinant parvovirus B19 viral proteins as antigen. The test procedure involves three incubation steps.

Manufacturer	Zeus Scientific, Inc
Number	P150042
Filing Date	11/27/2015
Approval Date	09/19/2017
Approved, Indicated Pediatric Subpopulation:	Pediatric patients[29]
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	349
Total Review Days	662

FreeStyle Libre Flash Glucose Monitoring System

The FreeStyle Libre Flash Glucose Monitoring System (FreeStyle Libre System, System, or Libre) uses an electrochemical sensor to monitor glucose levels in interstitial fluid (ISF). The sensor is held in place by an adhesive and incorporates both the subcutaneously implanted sensor and associated electronics. The sensor uses a glucose oxidase enzyme to oxidize glucose and transfer electrons to a metal electrode, producing a current. The strength of the current is proportional to the amount of glucose present in the subcutaneous space. The system converts the electrical current signal to a glucose value for display to the user on a handheld Reader.

Manufacturer	Abbott Diabetes Care Inc.
Number	P160030
Filing Date	08/01/2016
Approval Date	09/27/2017
Approved, Indicated Pediatric Subpopulation:	18 and older

[29] This pediatric device approval does not specify pediatric subpopulations.

Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	178
Total Review Days	422

HDE Device Information

Flourish™ Pediatric Esophageal Atresia Device

The Flourish Pediatric Esophageal Atresia Device consists of an oral/esophageal catheter and a gastric catheter. The oral/esophageal catheter is a 10 Fr two-lumen catheter. One lumen is for injection of contrast to confirm anastomosis; the other is for suction of saliva.
The gastric catheter is a modified two-lumen 18 Fr/ 5 cc balloon retention catheter. One lumen is for balloon inflation/deflation. The second lumen is modified by the addition of the gastric magnet catheter, essentially creating a lumen within a lumen. This modified arrangement allows for initial placement of a wire to guide introduction of the gastric magnet catheter assembly. Once the wire guide is removed from the gastric magnet catheter, flushing can occur through this created lumen or through an added accessory lumen.

Manufacturer	Wilson-Cook Medical Inc.
Number	H150003
Filing Date	12/21/2015
Approval Date	05/12/2017
Approved, Indicated Pediatric Subpopulation:	Up to one year
Exempt from User Fees because intended solely for pediatric use?	N/A[30]
FDA Review Days	147
Total Review Days	508

PulseRider® Aneurysm Neck Reconstruction Device ("PulseRider")

The PulseRider Aneurysm Neck Reconstruction Device is a self-expanding nitinol implant designed to retain neurovascular embolic coils in unruptured wide-necked intracranial aneurysms with neck widths $\geq$ 4 mm or dome to neck ratio < 2 originating on or near a vessel bifurcation of the basilar tip or carotid terminus with at least a portion of the aneurysm neck overlapping the lumen of the parent artery. The inflow vessels should have diameters from 2.7 mm to 4.5 mm. The PulseRider Aneurysm Neck Reconstruction Device is comprised of a torque device, delivery wire, introducer, and implant.

The implant is provided attached to the delivery wire. The delivery wire has a working length of 190 cm and a nominal diameter of 0.36 mm (0.014"). The introducer has a working length of 67 cm and a nominal diameter of 1.32 mm (0.052"). The PulseRider implant and delivery wire are insulated to allow electrolytic current to be delivered to the detachment junctions using commercially available detachment controllers. The torque device provided may be attached to the proximal end of the delivery wire to aid in orienting the implant prior to detachment.

Manufacturer	Pulsar Vascular, Inc.
Number	H160002

[30] N/A means "not applicable" since all HDEs are exempt from user fees, whether or not solely indicated for pediatric use.

Filing Date	06/15/2016
Approval Date	06/19/2017
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	N/A
FDA Review Days	296
Total Review Days	369

Appendix B

Table 1. Total PMA and HDE Approvals and PMA and HDE Approvals with a Pediatric Indication from FY2008-FY2017. [31]

FY	2008	2009	2010	2011	2012	2013	2014	2015	2016	2017
Total Approved PMA and HDE Devices	29	31	20	41	52	39	37	61	71	66
Number (%) of PMA and HDE Devices Indicated for Pediatric Patients	4 (14%)	7 (22.6%)	7 (35%)	17 (41.5%)	11 (21.2%)	8 (20.5%)	8 (21.6%)	11 (21.6%)	13 (18.3%)	18 (27%)

Table 2. PMA and HDE Approvals Indicated for Pediatric Subpopulations by Age from FY2013-FY2017 (devices were categorized by the youngest age for which there is an indication for use).[32]

	Pediatric Subcategory	Year					Total
		2013	2014	2015	2016	2017	
PMA	Neonates (birth - 28 days)	0	1	0	0	2	3
	Infants (29 days to <2 years)	0	0	0	0	0	0
	Children (2 - 12 years)	0	1	3	2	8	14
	Adolescents (12 - 21 years)	8	4	7	11	6	36
HDE	Neonates (birth - 28 days)	0	1	0	0	1	2
	Infants (29 days to <2 years)	0	0	0	0	0	0
	Children (2 - 12 years)	0	1	0	0	0	1
	Adolescents (12 - 21 years)	0	0	1	0	1	2
	Total	8	8	11	13	18	58

[31] Data cleaning was conducted for prior years that indicated inconsistencies with accounting identified in prior reports. This appendix reflects the most up-to-date numbers. The methodology used for data cleaning included the following: 1) reexamination of the indications for use as stated in the SSED or SSPB; and 2) determination if years of age in number form and/or the word "pediatrics" was explicitly identified in the SSED or the SSPB.

[32] Data cleaning was conducted for prior years that indicated inconsistencies with accounting identified in prior reports. This document reflects the most up-to-date numbers.