Report to Congress

FY 2016 PREMARKET APPROVAL OF PEDIATRIC USES OF DEVICES

Submitted Pursuant to

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

U.S. Food and Drug Administration

Scott Gottlieb MD Date 8/1/17

Scott Gottlieb, M.D.
Commissioner of Food and Drugs

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 the Agency) to submit an annual report to Congress that provides information concerning the premarket approval of devices labeled for pediatric use or for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure. This is FDA's seventh report pursuant to this requirement. The report provides information from FDA's Center for Devices and Radiological Health and reflects device approvals during fiscal year (FY) 2016 (October 1, 2015, through September 30, 2016). This report highlights the following information:

- FDA approved 68 original and panel track supplement premarket approval applications (PMA) and 3 humanitarian device exemption (HDE) applications.

- Of the 71 total approvals, 62 PMAs and all 3 HDE applications were approved to treat, diagnose, or cure a disease or condition which occurs within a pediatric subpopulation.

- Of the 71 total approvals, FDA approved 13 PMAs and no HDE applications indicated for use in a pediatric population or subpopulation. Information about each FY 2016 pediatric device approval, including its review time and the pediatric population for which it is indicated, appears in this report within Appendix A.

- Of the 71 total approvals, 2 were intended solely for pediatric use and were therefore exempted from user fees.

- The median time to review the 13 PMAs labeled for use in a pediatric population was 180 FDA Days and 267 total elapsed review days.[1]

[1] The term "FDA Days" is defined in the Medical Device User Fee Act III Commitment Letter here: https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.

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I. Introduction

The Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85) amended section 515A of the Federal Food, Drug, and Cosmetic Act (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 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. Such information assisted in developing this report. Section 515A(a)(3) of the FD&C Act requires the Food and Drug Administration (FDA or the Agency) to submit an annual report to Congress that provides information concerning the premarket approval of devices labeled for pediatric use or for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure.

Specifically, section 515A(a)(3) of the FD&C Act states that:

> *"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 is submitted, for which there is a pediatric subpopulation that suffers from the disease or condition that the device is intended to treat, diagnose, or cure;*
>
> *(B) the number of devices approved in the year preceding the year in which the report is submitted, labeled for use in pediatric patients;*
>
> *(C) the number of pediatric devices approved in the year preceding the year in which the report is submitted that were exempted from a fee pursuant to section 738(a)(2)(B)(v); and*
>
> *(D) the review time for each device described in subparagraphs (A), (B), and (C).*"

This is FDA's seventh report pursuant to section 515A(a)(3) of the FD&C Act since FDAAA's enactment. The report provides the data and information required under section 515A(a)(3) of the FD&C Act for approvals made during FY 2016, as well as 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:

> "*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.*
>
> *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.*"[2]

For the purposes of this report, pediatric use devices are those which are indicated for use in pediatric patients or intended to treat, diagnose, or cure diseases from which pediatric patients suffer. In addition, for the purposes of this report, the pediatric population is defined as those younger than 22 years of age (i.e., inclusive of the patient's 21st year of life). Pediatric subpopulations are defined in section 520(m)(6)(E)(ii) (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);[3]
- Infants (1 month until 2 years of age);
- Children (2 years until 12 years of age); and
- Adolescents (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 (79 FR 1735) amending the PMA 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. These requirements are mandated by section 515A of the FD&C Act (as added by FDAAA).[4]

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

[3] See *Pediatrics* 2011; 128:177-181; American Academy of Pediatrics; American College of Obstetrics and Gynecology: Appendix D: standard terminology for reporting reproductive health statistics. In: *Guidelines for Perinatal Care.* 6th ed. Elk Grove Village, Il: American Academy of Pediatrics; 2007: 389-404.

[4] "21 CFR Part 814; Medical Devices; 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," 79 Federal Register 7 (10 January 2014), pp. 1735-1741 (79 FR 1735).

On May 1, 2014, FDA issued a final guidance document titled "Providing Information about Pediatric Uses of Medical Devices." [5] The final guidance provides information for applicants regarding the pediatric information requirement in a question-and-answer format.[6]

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

In summary, in FY 2016:

- FDA approved 68 original and panel track supplement PMAs and 3 HDE applications.
- Of the 71 total approvals, 2 PMAs were intended solely for pediatric use and therefore exempted from user fees.
- Of the 71 approvals, 62 PMAs and 3 HDEs were approved to treat, diagnose, or cure a disease or condition which occurs within a pediatric subpopulation. Of these, 13 (all PMAs) were approved specifically with an indication for a pediatric population or subpopulation.
- Of the 13 devices that have pediatric indications, 3 devices are for pediatric populations less than 18 years old.
- None of the HDE devices were indicated for use in a pediatric population.
- The median time to review the 13 PMAs labeled for use in a pediatric population was 180 FDA Days and 267 total elapsed review days.[7]

Table 1 and Figure 1 below depict the numbers of PMAs and HDE applications approved since 2008.

[5] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM339465.pdf

[6] There is an additional guidance, "Leveraging Clinical Data for Extrapolation to Pediatric Uses of Medical Devices," which was finalized in 2016. https://www.fda.gov/ucm/groups/fdagov-public/@fdagov-meddev-gen/documents/document/ucm444591.pdf

[7] The term "FDA Days" is defined in the Medical Device User Fee Act III Commitment Letter here: https://www.fda.gov/downloads/MedicalDevices/NewsEvents/WorkshopsConferences/UCM295454.pdf.

Table 1. Total Approved PMA and HDE Devices vs. Approved PMA and HDE Devices with a Pediatric Indication

FY Year	2008	2009	2010	2011	2012	2013	2014	2015	2016
Total Approved PMA and HDE Devices	29	31	20	42	51	39	37	61	71
Number (%) of PMA and HDE Devices Indicated for Pediatric Patients	2 (6.9%)	2 (6.5%)	8 (40.0%)	15 (35.7%)	11 (21.6%)	8 (20.5%)	8 (21.6%)	11 (21.6%)	13 (18.3%)

Figure 1. Approved Pediatric and Non-Pediatric PMA and HDE Devices, 2008-2016

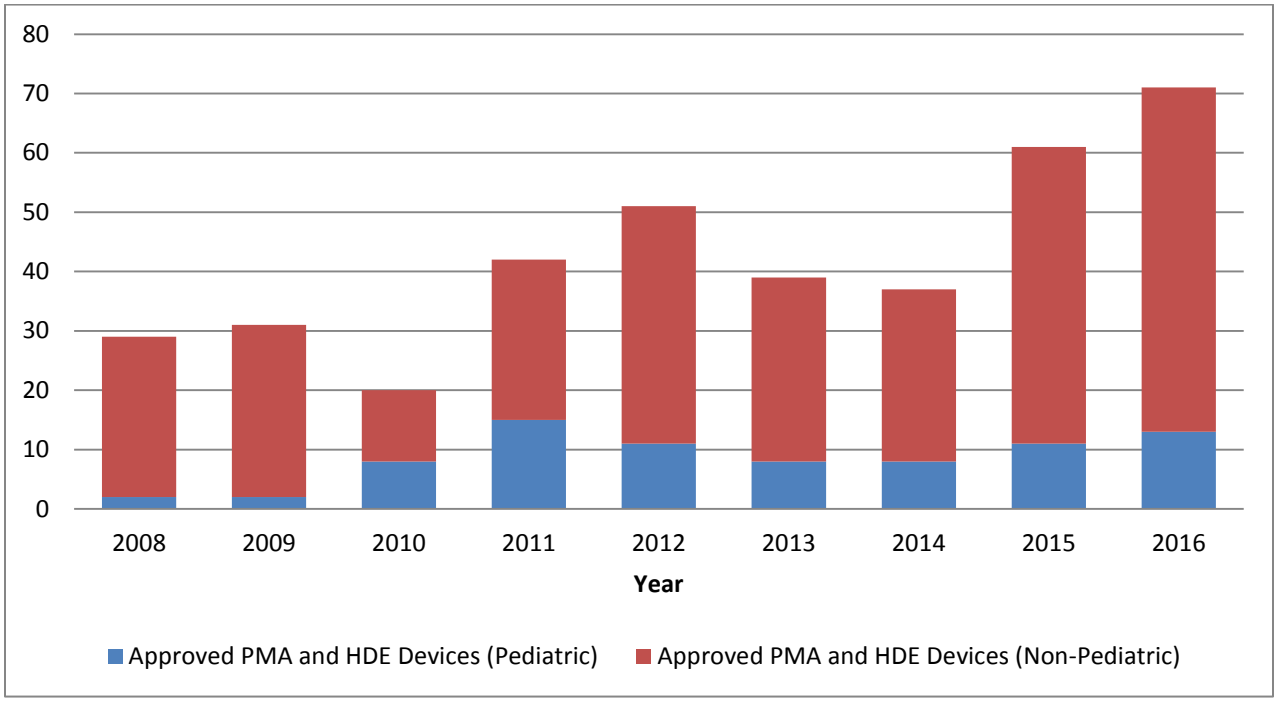

Figure 1 shows the number of PMA and HDE device approvals that were indicated for use in a pediatric population or pediatric subpopulation over a 9-year period (in blue), as well as the number of non-pediatric PMA and HDE devices approved in that year (in red). The largest number of devices approved for a pediatric indication was in 2011 with the largest percentage in 2010. Across the 9 years, an average of almost nine devices were approved per year that were indicated for pediatric patients; this equated to an average of 20.5 percent of PMAs and HDEs over this time. There were no apparent trends in numbers or percentages.

IV. Conclusion

This FY 2016 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 by section 515A of the FD&C Act. Appendix A includes a more detailed summary for each of the FY2016 PMA device approvals that were labeled for use in a pediatric population or subpopulation.

Appendix A:
FY 2016 Device Approvals Indicated for Use in Pediatric Patients with Review Times

FY 2016	
PMA Device Information	
MiniMed 530G Insulin Pump The MiniMed 530G insulin pump is an ambulatory, battery operated, rate-programmable infusion pump designed to deliver insulin from a reservoir. The reservoir is driven by a motor to deliver patient determined basal rate profiles and patient selected bolus amounts of insulin into the subcutaneous tissue through an infusion set.	
Manufacturer	Medtronic, Inc.
Number	P120010/S046
Filing Date	12/22/2014
Approval Date	10/02/2015
Approved, Indicated Pediatric Subpopulation:	16 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	179
Total Review Days	284
Med-El Cochlear Implant System The Med-El Cochlear Implant System detects and recognizes auditory information through electrical stimulation of the auditory nerve for severe to profoundly hearing-impaired individuals who obtain little or no benefit from conventional acoustic amplification in the best-aided condition. The current supplement was submitted to expand the indication for the Med-El Cochlear Implant System to include the Med-El EAS System. The Med-El EAS System is intended to provide electrical stimulation to the mid- to high-frequency region of the cochlea and acoustic amplification to the low-frequency regions, for candidates with residual low frequency hearing sensitivity.	
Manufacturer	MED-EL Corp.
Number	P000025/S084
Filing Date	12/23/2015
Approval Date	09/15/2016
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	267

LifeVest Wearable Defibrillator

The LifeVest Wearable Defibrillator is the first wearable defibrillator, and it is worn outside of the body. This device continuously monitors the patient's heart with dry non-adhesive sensing electrodes to detect life-threatening abnormal heart rhythms. If a life-threatening rhythm is detected, the device alerts the patient prior to delivering a treatment shock. A conscious patient is thus allowed to delay the treatment shock. If the patient becomes unconscious, the device releases a Blue™ gel over the therapy electrodes and delivers an electrical shock to restore normal rhythm.

Manufacturer	ZOLL Manufacturing Corporation
Number	P010030/S056
Filing Date	02/19/2013
Approval Date	12/17/2015
Approved, Indicated Pediatric Subpopulation:	18 and younger
Exempt from User Fees because intended solely for pediatric use?	Yes
FDA Review Days	1,031
Total Review Days	1,031

Animas Vibe System

The Animas Vibe System ("Vibe System") consists of the Animas Vibe Insulin Pump ("The Pump") and Dexcom G4 Platinum CGM System. The Vibe System includes an insulin infusion pump that is designed to communicate via Radio Frequency (RF) telemetry with the Dexcom CGM transmitter ("the Transmitter") to display CGM information in addition to infusion pump data. The insulin infusion pump delivers insulin through an infusion set for continuous subcutaneous insulin infusion for the management of insulin-requiring diabetes. The Dexcom G4 CGM System ("the Sensor") provides continuous measurements of glucose in the tissue over the range of 40 to 400 mg/dL for up to 7 days of use and displays 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 Corp.
Number	P130007/S004
Filing Date	04/30/2015
Approval Date	12/24/2015
Approved, Indicated Pediatric Subpopulation:	2 and older
Exempt from User Fees because intended solely for pediatric use?	Yes
FDA Review Days	198
Total Review Days	238

STORZ Medical Duolith SD1 Shock Wave Therapy

The STORZ Medical Duolith SD1 Shock Wave generates shockwaves for therapy. It has a control unit and a hand piece. Therapists use the hand piece to direct waves and change how deep the waves go into the body. The STORZ Medical Duolith SD1 Shock Wave makes a shock wave by discharging a capacitor into a coil in the hand piece. The magnetic field in the coil creates eddy currents in a metal sheet. This causes the metal sheet to move away from the coil. Because the metal sheet is in water, it makes a pressure wave. A reflector focuses the pressure wave in tissue. Pressure waves can cause changes in tissue. These changes can lead to healing.

Manufacturer	STORZ Medical AG
Number	P080028
Filing Date	11/26/2008
Approval Date	01/08/2016
Approved, Indicated Pediatric Subpopulation:	Older than 18
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	679
Total Review Days	2,599

The Edwards SAPIEN XT Transcatheter Heart Valve (THV)

The Edwards SAPIEN XT THV is comprised of a balloon-expandable, radiopaque, cobalt chromium frame; trileaflet bovine pericardial tissue valve; and polyethylene terephthalate (PET) fabric skirt. The leaflets are treated according to the Edwards ThermaFix™ process, and the valve is packaged and terminally sterilized in glutaraldehyde.

Manufacturer	Edwards Lifesciences, LLC
Number	P130009/S037
Filing Date	07/01/2015
Approval Date	02/29/2016
Approved, Indicated Pediatric Subpopulation:	Pediatric and Adult Patients
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	180
Total Review Days	243

PROPEL Mini Sinus Implant

The PROPEL Mini Sinus Implant separates/dilates surrounding mucosal tissues, provides stabilization of the middle turbinate, prevents obstruction by adhesions, and reduces inflammation. The implant reduces the need for post-operative intervention such as surgical adhesion lysis and/or use of oral steroids.

Manufacturer	Intersect ENT
Number	P100044/S018
Filing Date	09/25/2015
Approval Date	03/23/2016
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	180

Cobas HPV Test, 240 Tests; Cobas HPV Test, 960 Tests

The Cobas HPV Test, 240 Tests; Cobas HPV Test, 960 Tests is a qualitative in vitro test for the detection of Human Papillomavirus (HPV) in cervical specimens collected by a clinician using an endocervical brush/spatula and placed in the ThinPrep® Pap TestTM PreservCyt® Solution or using a cervical broom and placed in SurePath Preservative Fluid. The test utilizes amplification of target DNA by the Polymerase Chain Reaction (PCR) and nucleic acid hybridization for the detection of 14 high-risk (HR) HPV types in a single analysis. The test specifically identifies types HPV16 and HPV18 while concurrently detecting the rest of the high-risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66 and 68).

Manufacturer	Roche Molecular Systems, Inc.
Number	P100020/S017
Filing Date	01/12/2016
Approval Date	07/07/2016
Approved, Indicated Pediatric Subpopulation:	21 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	177
Total Review Days	177

MiniMed 630G System with SmartGuard™

The MiniMed 630G System with SmartGuard™ is intended for continuous delivery of basal insulin (at user selected rates) and administration of insulin boluses (in user selectable amounts) for the management of diabetes mellitus as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin. The SmartGuard™ can be programmed to temporarily suspend delivery of insulin for up to 2 hours when the sensor glucose value falls below a predefined threshold value.

Manufacturer	Medtronic Minimed
Number	P150001
Filing Date	01/09/2015
Approval Date	08/10/2016
Approved, Indicated Pediatric Subpopulation:	16 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	338
Total Review Days	579

Blazer Open-Irrigated Ablation Catheter

The Blazer Open-Irrigated Ablation Catheter is a 7.5F (2.5 mm) quadrapolar openirrigated ablation catheter designed to deliver radiofrequency (RF) energy to the 4 mm catheter tip electrode for cardiac ablation. The device is designed to be used in conjunction with the Open-Irrigated System, which is inclusive of the Maestro 4000™ Cardiac Ablation System, MetriQ™ Irrigation Pump, MetriQ™ Irrigation Tubing Set, and associated cables.

Manufacturer	Boston Scientific Corp.
Number	P150005
Filing Date	02/02/2015
Approval Date	02/24/2016
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	387

Paradigm REAL-Time Revel System

The Paradigm REAL-Time Revel System is comprised of an insulin pump, subcutaneously inserted glucose sensor, and transmitter which relays information from the glucose sensor to the insulin pump.

Manufacturer	Medtronic Minimed
Number	P150019
Filing Date	06/10/2015
Approval Date	12/07/2015
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	180

Freestyle Libre Pro Flash Glucose Monitoring System

The FreeStyle Libre Pro Flash Glucose Monitoring System (FreeStyle Libre Pro System) aids in the detection of glucose level excursions above or below the desired range, facilitating therapy adjustments. The FreeStyle Libre Pro System uses a subcutaneously implanted electrochemical sensor, which incorporates the same wired enzyme glucose sensing technology utilized in the FreeStyle Navigator® Continuous Glucose Monitoring System (approved in March 2008), to monitor glucose levels in interstitial fluid.

Manufacturer	Abbott Diabetes Care Inc.
Number	P150021
Filing Date	06/22/2015
Approval Date	09/23/2016
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	176
Total Review Days	459

MiniMed 670G System

The Medtronic MiniMed 670G system is intended for continuous delivery of basal insulin (at user selectable rates) and administration of insulin boluses (in user selectable amounts) for the management of Type 1 diabetes mellitus as well as for the continuous monitoring and trending of glucose levels in the fluid under the skin.

The MiniMed 670G System includes SmartGuard™ technology, which can be programmed to automatically adjust delivery of basal insulin based on Continuous Glucose Monitor sensor glucose values, and can suspend delivery of insulin when the sensor glucose value falls below or is predicted to fall below predefined threshold values.

Manufacturer	Medtronic Minimed
Number	P160017
Filing Date	06/17/2016
Approval Date	09/28/2016
Approved, Indicated Pediatric Subpopulation:	14 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	103
Total Review Days	103