REPORT TO CONGRESS

Premarket Approval of Pediatric Uses of Devices – FY 2015

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

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Executive Summary

Section 515A(a)(3) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) requires the Food and Drug Administration (FDA) to submit an annual report to Congress that provides information concerning premarket approvals of devices labeled for pediatric use or for which there is a pediatric subpopulation that suffers from the disease that the device is intended to treat, diagnose, or cure. This is FDA's sixth report pursuant to this requirement. The report provides information from FDA's Center for Devices and Radiological Health and reflects approvals made during fiscal year (FY) 2015 (October 1, 2014, through September 30, 2015). This report highlights the following information:

Final decisions in FY 2015:

- FDA approved 57 original and panel track supplement premarket approval applications (PMA) and 4 humanitarian device exemption (HDE) applications.

- Among the 61 total approvals, 46 PMAs and 2 HDE applications were approved for the treatment, diagnosis, or cure of a disease or condition which occurs within a pediatric subpopulation.

- Among the 61 total approvals, FDA approved 10 PMA s and 1 HDE application indicated for use in a pediatric population or subpopulation.

- Among the 61 total approvals, 1 PMA was exempted from user fees as it was intended solely for pediatric use.

- Information about each FY 2015 pediatric device approval, including its review time and the pediatric population for which it is indicated, appears in Appendix A of this report.

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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 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 FDA to submit an annual report to Congress that provides information concerning premarket approvals 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:*
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> *(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 sixth 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 2015, 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.*[1]

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 who have not yet turned 22. 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);[2]
- Infants (1 month until 2 years of age);
- Children (2 years until 12 years of age); and
- Adolescents (12 years until 22 years of age).

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, added by FDAAA.[3]

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[1] 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.

[2] 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.

[3] "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."[4] The final guidance provides information for applicants regarding the pediatric information requirement in a question-and-answer format.[5]

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

In summary, in FY 2015:

- FDA approved 57 original and panel track supplement PMAs and 4 HDE applications.
- Among the 61 total approvals, 1 PMA device was exempted from user fees as it was intended solely for pediatric use.
- Among the 61 approvals, 46 PMA and 2 HDE devices were approved for the treatment, diagnosis, or cure of a disease or condition which occurs within a pediatric subpopulation, of which 10 PMA and 1 HDE devices were indicated for use in a pediatric population or subpopulation.

    I. The 1 HDE device indicated for use in a pediatric population met the criteria under Section 520(m)(6)(A)(i) that the devices may be sold for an amount that exceeds the cost of research and development, fabrication, and distribution of the device (i.e., for profit) as long as the number of devices distributed in any calendar year does not exceed their annual distribution number (ADN).[6]

    II. Among the 10 PMA and 1 HDE devices labeled for use in a pediatric population or subpopulation, there was a median of 179 FDA review days and 237 total elapsed review days.[7]

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

[5] 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

[6] The ADN is based on the number of individuals likely to use the device and the number of devices reasonably necessary to treat such individuals.

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

Figures 1 and 2 below depict the number of PMAs and HDEs approved since 2008.

Total Approved PMA and HDE Devices vs. Percentage of Pediatric-Indicated PMA and HDE Devices								
FY Year	**2008**	**2009**	**2010**	**2011**	**2012**	**2013**	**2014**	**2015**
Total Approved PMA and HDE Devices	29	31	20	42	51	39	37	61
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 (18.0%)

Figure 1. The above table shows the total number of PMA and HDE devices that were approved in a given year, along with the number and percentage of PMA and HDE devices that were approved for use in a pediatric population or subpopulation in the corresponding year.

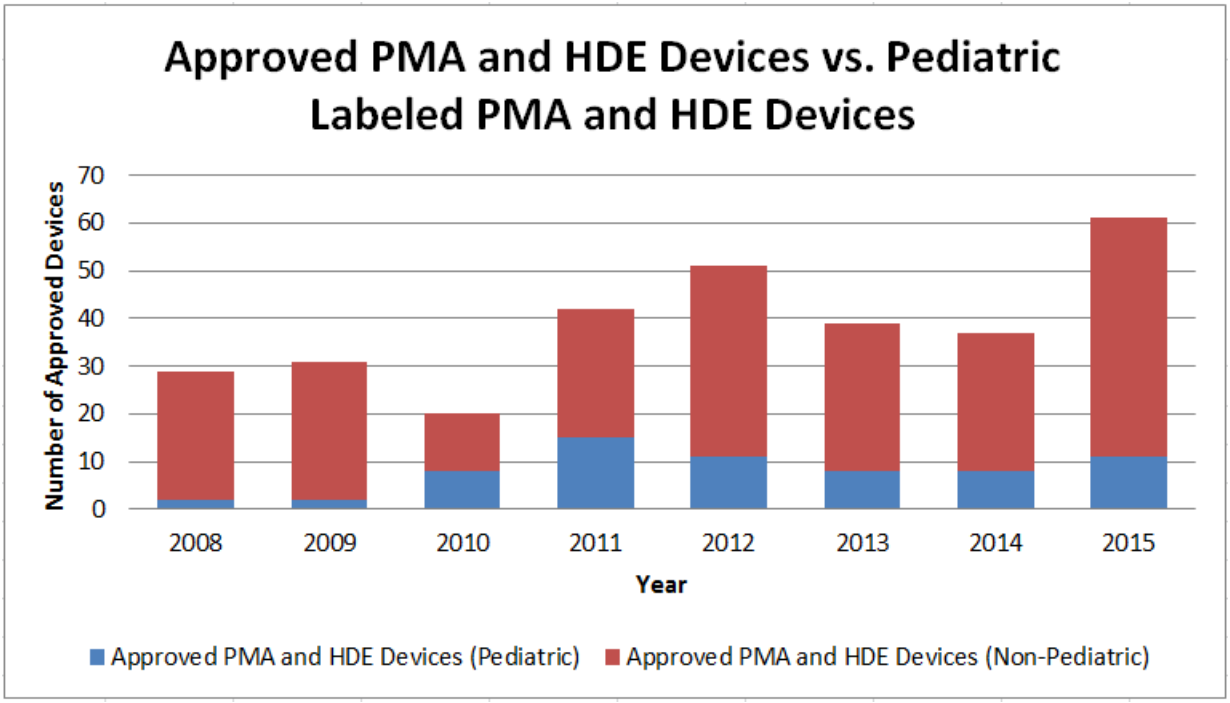

Figure 2. The graph above shows the number of PMA and HDE device approvals that were indicated for use in a pediatric population or subpopulation over an 8-year period (in blue), as well as the number of non-pediatric PMA and HDE devices approved in that year (in red). The largest number of devices approved for a pediatric indication was in 2011. Over the 8 years there was an average of eight devices per year, which equated to an average of 21.4 percent of PMAs and HDEs over this time that were indicated for pediatric patients; there were no apparent trends in numbers or percentages.

IV. Conclusion

This FY 2015 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 FY2015 PMA and HDE device approvals that were labeled for use in a pediatric population or subpopulation.

Appendix A
FY 2015 Device Approvals Indicated for Use in Pediatric Patients with Review Times

FY 2015

PMA Device Information

Dexcom G4 PLATINUM Continuous Glucose Monitoring System

The Dexcom G4 PLATINUM Continuous Glucose Monitoring (CGM) System is an externally-worn system with an internal sensor that continuously measures and displays glucose values in the fluid between the body's cells (interstitial fluid). In addition to reporting interstitial glucose values every 5 minutes, the system reports trending information in real-time for up to 7 days (the life of each sensor). This new version updates the software that calculates the interstitial glucose values from the sensor signal.

Manufacturer	Dexcom, Inc.
Number	P120005/S018
Filing Date	4/25/2014
Approval Date	10/21/2014
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	179
Total Review Days	179

Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System

The Dexcom G4 PLATINUM (Pediatric) Continuous Glucose Monitoring System (Pediatric CGM System) is an externally-worn glucose sensor that continuously measures and displays glucose values. In addition to reporting glucose values every 5 minutes, the system reports trending information in real-time for up to 7 days (the life of each sensor).

Manufacturer	Dexcom, Inc.
Number	P120005/S031
Filing Date	11/26/2014
Approval Date	5/22/2015
Approved, Indicated Pediatric Subpopulation:	Ages 2-17
Exempt from User Fees because intended solely for pediatric use?	Yes
FDA Review Days	177
Total Review Days	177

IDEAL IMPLANT Saline-filled implants

The IDEAL IMPLANT Saline-filled Breast Implant consists of multiple silicone shells within an outer shell. It has two valves that fill the device with saline. The IDEAL IMPLANT Saline-filled Breast Implant is available in a variety of sizes.

Manufacturer	IDEALIMPLANT
Number	P120011
Filing Date	6/25/2012
Approval Date	11/14/2014
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	770
Total Review Days	872

Animas® Vibe™ System

The Animas Vibe System is a continuous glucose monitor (CGM) and insulin pump combination for people with diabetes. The CGM is an externally-worn device with an internal sensor that continuously measures glucose values in the fluid around the cells (interstitial glucose) for up to 7 days (the life of the sensor). The insulin pump delivers insulin as a single dose (bolus) when needed or continuously throughout the day (basal insulin). The insulin pump displays glucose values from the CGM along with glucose trending information, alerts and alarms, and insulin pump data and information.

Manufacturer	Animas Corp.
Number	P130007
Filing Date	4/25/2013
Approval Date	11/25/2014
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	179
Total Review Days	579

Adherus® AutoSpray Dural Sealant

The Adherus AutoSpray Dural Sealant is used in brain surgery and is applied over stitches (sutures) for dura repair to prevent cerebrospinal fluid (CSF) from leaking out of the incision site. The dura is the membrane that covers the brain and spinal cord. The Adherus AutoSpray Dural Sealant consists of synthetic, absorbable sealant materials and a single-use, battery-operated applicator.

Manufacturer	Hyperbranch Medical Technology, Inc.
Number	P130014
Filing Date	6/12/2013
Approval Date	3/30/2015
Approved, Indicated Pediatric Subpopulation:	13 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	180
Total Review Days	656

MAESTRO® Rechargeable System

The Maestro Rechargeable System is a weight-loss treatment for patients who are morbidly obese or who are obese with one or more obesity-related conditions. The Maestro Rechargeable System contains some components that are implanted inside the body and some that are outside the body. The internal components include a rechargeable pulse generator (also called a neuroregulator disc) which delivers electrical signals to nerve electrodes. The electrodes are placed on the trunks of the vagus nerve in the abdomen and two electrical leads connect the electrodes to the pulse generator. The external components include a transmit coil, mobile charger, and clinician programmer.

Manufacturer	Enteromedics, Inc.
Number	P130019
Filing Date	6/24/2013
Approval Date	1/14/2015
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	501
Total Review Days	569

t:slim G4™ Insulin Pump with Dexcom G4® Platinum CGM

The t:slim G4 System is made up of the t:slim® G4 Insulin Pump, the Dexcom G4 PLATINUM Sensor, and the Dexcom G4 PLATINUM Transmitter. The t:slim G4 Insulin Pump delivers insulin in two ways: continuous, or basal insulin delivery, and bolus insulin delivery to cover carbohydrates eaten (food bolus) and to lower high blood glucose (correction bolus). A disposable cartridge is filled with up to 300 units of insulin and attached to the pump. The cartridge is replaced every few days.

Manufacturer	Tandem Diabetes Care, Inc.
Number	P140015
Filing Date	7/17/2014
Approval Date	9/8/2015
Approved, Indicated Pediatric Subpopulation:	12 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	180
Total Review Days	418

Melody Transcatheter Pulmonary Valve, Ensemble Transcatheter Valve Delivery System

The Medtronic Melody Transcatheter Pulmonary Valve (TPV) is an artificial heart valve made from the jugular vein valve of a cow that is sewn into a small metal frame. The Medtronic Ensemble Transcatheter Valve Delivery System is a thin, hollow, and long tube (catheter) that delivers the Melody TPV into the heart without open heart surgery while the heart is beating.

Manufacturer	Medtronic, Inc.
Number	P140017
Filing Date	8/21/2014
Approval Date	1/27/2015
Approved, Indicated Pediatric Subpopulation:	Pediatric or adult patients with a (circumferential) RVOT conduit that was equal to or greater than 16 mm in diameter at the time of implantation
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	159
Total Review Days	159

Elecsys Anti-HCV II Immunoassay, Elecsys Precicontrol Anti-HCV

The Elecsys® Anti-HCV II Immunoassay is a laboratory test used to detect human antibodies against the hepatitis C virus (HCV). The presence of antibodies against HCV can help determine if a person has been exposed to HCV but will not be able to tell if a person is acutely infected, chronically infected with HCV, or recovered from HCV infection. This test is designed for use on the cobas e 601 immunoassay analyzer which runs the assay and analyzes the results.

The Elecsys® PreciControl Anti-HCV is used as a quality control to ensure that the test is working properly.

Manufacturer	Roche Diagnostics Operations, Inc.
Number	P140021
Filing Date	10/17/2014
Approval Date	6/11/2015
Approved, Indicated Pediatric Subpopulation:	18 months – 21 years
Exempt from User Fees because intended solely for pediatric use?	No[8]
FDA Review Days	159
Total Review Days	237

[8] These devices were approved as a bundled submission. The Immunoassay is solely for pediatric use, but the Preci-Control Anti-HCV is not limited in age. The Immunoassay would have been eligible for fee exemption if the submission was not bundled to include a device with the intended use outside of pediatric usage and so not exempt from fee. For more information about bundled submissions, please refer to the following guidance: https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm089732.pdf

STAR S4 IR Excimer Laser System and iDesign Advanced WaveScan Studio System

The STAR S4 IR Excimer Laser System (Laser System) and iDesign Advanced WaveScan Studio System (iDesign System) reduces or eliminates nearsightedness (myopia) and/or astigmatism (a refractive error in which the eye focuses light rays more strongly in one direction than another).

In addition to the laser itself, the Laser System includes an eye-tracker that keeps the laser pulses correctly positioned on the cornea when the eye moves.

The iDesign System includes an aberrometer that measures and records the power of the eye as well as the size and position of the pupil; a corneal topographer that measures the shape of the cornea; and treatment planning software that converts the data from the aberrometer into detailed instructions for the excimer laser treatment.

Manufacturer	Amo Manufacturing USA, LLC.
Number	P930016/S044
Filing Date	11/10/2014
Approval Date	5/6/2015
Approved, Indicated Pediatric Subpopulation:	18 and older
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	177
Total Review Days	177

Impella RP System

The Impella RP System includes a mini heart pump mounted at the end of a thin, flexible tube (catheter), a console that drives the pump, and an infusion pump that flushes the pump. The heart pump can be implanted in the right side of the heart without open chest surgery to help pump blood in patients who need short-term support.

Manufacturer	Abiomed, Inc.
Number	H140001
Filing Date	9/10/2014
Approval Date	1/23/2015
Approved, Indicated Pediatric Subpopulation:	Pediatric or adult patients with a body surface area ≥1.5 m2
Exempt from User Fees because intended solely for pediatric use?	No
FDA Review Days	135
Total Review Days	135