DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
Silver Spring, MD 20993

March 17, 2009

TO: The Secretary
Through: DS _____
COS ____
ES _____

FROM: Acting Commissioner of Food and Drugs

SUBJECT: Report to Congress Required by Section 515A(a)(3) of the Food and Drug Administration Amendments Act of 2007 (FDAAA)

Attached for your consideration is the Food and Drug Administration's (FDA's) Report to Congress regarding the premarket approval of devices that may be used in pediatric patients, as required by section 302 of FDAAA (Public Law 110-85), which the President signed into law on September 27, 2007. Section 302, which added new section 515A(a)(3) to the Federal Food, Drug, and Cosmetic Act (Act), requires FDA to provide an annual report with information concerning premarket approvals of devices that may be used in pediatric patients. This is FDA's first report pursuant to this requirement. The report uses information from FDA's Center for Devices and Radiological Health, and reflects approvals made during fiscal year (FY) 2008.

The report provides background information about the history of FDA's activities to promote the development of safe and effective pediatric devices and to protect the pediatric subpopulations during the course of clinical trials. It then provides the data and information required under section 515A(a)(3) of the Act for approvals made during FY 2008.

In FY 2008, 15 out of 27 premarket approval applications (PMAs) and 2 humanitarian device exemptions were approved for diseases or conditions from which a pediatric subpopulation may suffer. Two of the 15 PMAs were labeled for use in pediatric patients. None of the device applications approved was exempt from user fees because they did not propose conditions of use intended solely for a pediatric population.

RECOMMENDATION

I recommend that you review and approve the report and forward it to Congress.

Frank M. Torti, M.D., M.P.H.

Attachments (2)
Tab A – Report to Congress
Tab B – Transmittal Letters

03242009/011

Tab A

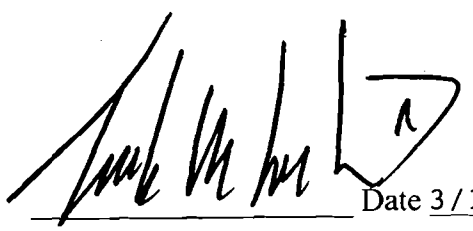
Report to Congress

Premarket Approval of Pediatric Uses of Devices — FY 2008

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



Date 3/17/09

Frank M. Torti, M.D., M.P.H.
Acting Commissioner of Food and Drugs

Executive Summary

Section 515A(a)(3) of the Federal Food, Drug, and Cosmetic Act[1] (FD&C Act) requires the Food and Drug Administration (FDA) to submit an annual report that provides information concerning premarket approvals of devices in terms of pediatric use. This is FDA's first report pursuant to this requirement. The report uses information from FDA's Center for Devices and Radiological Health (CDRH), and reflects approvals made during FY 2008.

As this is FDA's first report under section 515A, we provide additional background information about the history of FDA's activities to promote the development of safe and effective pediatric devices and to protect the pediatric subpopulations during the course of clinical trials. This report highlights the following information:

- Fifteen out of 27 original and panel track supplement PMAs, and 2 out of 2 HDE applications devices, were approved to treat, diagnose, or cure a disease or condition for which there is a pediatric subpopulation suffering from that disease or condition during the period from October 1, 2007 through September 30, 2008 (FY 2008.)
- Two devices approved during FY 2008 were labeled for use in pediatric patients.
- None of the 29 devices approved in FY 2008 were exempt from user fees because none had proposed conditions of use intended solely for a pediatric population.
- Information about each device approval, including its review time, appears in this report at Appendix A.

[1] Section 515A was added by section 302 of the Food and Drug Administration Amendments Act of 2007, P.L. 110-85.

Table of Contents

I. **Introduction**

In 2007, Congress passed the Food and Drug Administration Amendments Act of 2007 (FDAAA) (Public Law 110-85). The FDAAA amended the FD&C Act and added several new provisions to it.

Section 302 of the FDAAA added new section 515A, "Pediatric Uses of Devices," to the FD&C Act. 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, 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 report is FDA's first report pursuant to section 515A(a)(3) of FD&C Act since FDAAA's enactment. The report provides some background information regarding section 515A of the FD&C Act and our implementation of that provision. It then provides the data and information required under section 515A(a)(3) of the FD&C Act for approvals made during fiscal year (FY) 2008.

II. **Background**

A. **What Information Does Section 515A(a) of the FD&C Act Require?**

Section 515A(a) of the FD&C Act requires persons submitting an application under section 520(m) of the FD&C Act,[2] or an application (including a supplement to such an

[2] Applications under section 520(m) of the FD&C Act are commonly known as humanitarian device exemption applications (HDEs).

application) or a product development protocol under section 515 of the FD&C Act[3] 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.

For the purposes of this report, section 520(m)(6)(E)(ii) of the FD&C Act defines "pediatric subpopulation" to mean one of the following populations:

- Neonates
- Infants
- Children
- Adolescents

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. 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.[4]

B. How Has FDA Implemented Section 515A(a) of the FD&C Act?

FDA and Congress have both been interested in the development of pediatric medical devices. For example, the Medical Device User Fee and Modernization Act of 2002 (MDUFMA) (Public Law 107-250) added several new provisions to the Act to promote the development of safe and effective pediatric devices and to protect this vulnerable patient population during the course of clinical trials involving such products. As part of the implementation of these provisions, FDA issued two guidance documents. The first, *Guidance for Industry and FDA Staff - Pediatric Expertise for Advisory Panels* (available at: www.fda.gov/cdrh/ode/guidance/1208.html) implemented the instruction in section 515(c) of the Act to ensure, where appropriate, that advisory panels include or consult with one or more pediatric experts. The second, *Guidance for Industry and FDA Staff -*

[3] Applications under section 515 of the Act are commonly known as Premarket Approval Applications (PMAs).

[4] 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.

Premarket Assessment of Pediatric Medical Devices (available at: http://www.fda.gov/cdrh/mdufma/guidance/1220.html), also sought to ensure that pediatric expertise is available to FDA Advisory Panels, when appropriate, to help address the intent of the pediatric provisions of MDUFMA.

As another example, section 3 of the Medical Devices Technical Corrections Act of 2004 (Public Law 108-214) required the Secretary of Health and Human Services to submit a "report on the barriers to the availability of devices intended for the treatment or diagnosis of diseases and conditions that affect children." FDA sought comment from interested parties, including consumers, researchers, healthcare practitioners, members of the device industry, and professional and trade associations, by holding a stakeholder meeting and publishing a notice in the *Federal Register* requesting comment. FDA provided the report to Congress in October 2004. The report is available at: http://www.fda.gov/cdrh/pediatricdevices/rtc100104.html.

FDA also have examined specific pediatric device issues and issued guidance documents pertaining to pediatric device matters. For example, on January 26, 2006, FDA held a public workshop entitled, "FDA Workshop on Regulatory Process for Pediatric Mechanical Circulatory Support Devices (Ventricular Assist Devices)," which addressed the regulatory approval process for pediatric ventricular assist device approval (minutes available at: http://www.fda.gov/cdrh/meetings/012006workshop/minutes.html). More recently, working with the National Institutes of Health (NIH), FDA helped to develop a draft "Pediatric Device Development Plan" (available on the Internet at: http://www.nichd.nih.gov/about/meetings/2008/upload/Draft_FDA_Pediatric_Drug_Development_Plan.pdf). FDA, NIH, and the Agency for Healthcare Research and Quality worked together to form an Interagency Pediatric Devices Working Group. On July 23, 2008, the three agencies held a public workshop to:

- Inform the community of the current status of pediatric device development;
- Describe available mechanisms for device product registration;
- Describe available mechanisms for pediatric device project funding;
- Understand what stakeholders see to be important areas of study;
- Determine gaps in knowledge and where the needs for research are; and
- Discuss ways to gather the information needed to move ahead, such as overcoming barriers, handling logistics, determining classes of devices to study, and identifying available databases, registries, and surveillance systems.

Additionally, on August 5, 2008, FDA issued a draft guidance document titled, *Guidance for HDE Holders, Institutional Review Boards (IRBs), Clinical Investigators, and FDA Staff – Humanitarian Device Exemption (HDE) Regulation: Questions and Answers* (available at: http://www.fda.gov/cdrh/ode/guidance/1668.html). The guidance answers commonly asked questions about humanitarian use devices, including questions related to the pediatric device requirements set forth in FDAAA.

III. Specific Information to be Reported under Section 515A(a) of the FD&C Act

A. How Did FDA Organize the Information?

FDA has organized the information in this section to correspond with the information specified by the FD&C Act. Although FDA interpret 515A(a) to apply to applications received after enactment of FDAAA, FDA is providing information on all device approvals for FY 2008 including applications pending at the time of FDAAA enactment.

B. What is the Number of Devices Approved for Which There is a Pediatric Subpopulation Suffering from the Disease or Condition that the Device is Intended to Treat, Diagnose, or Cure?

Fifteen out of 27 original and panel track supplement PMAs, and 2 out of 2 HDE applications devices, were approved to treat, diagnose, or cure a disease or condition for which there is a pediatric subpopulation suffering from that disease or condition during the period from October 1, 2007 through September 30, 2008 (FY 2008.)

C. How Many Devices Were Approved and Labeled for Use in Pediatric Patients?

Two devices approved during FY 2008 were labeled for use in pediatric patients.

D. How Many Pediatric Devices Were Exempted from a Fee Pursuant to Section 738(a)(2)(B)(v) of the Act?

None of the 29 devices approved in FY 2008 were exempt from user fees because none had proposed conditions of use intended solely for a pediatric population.

E. What was the review time for each device described in subparagraphs (A), (B), and (C) of section 515A(a)(1)(3) of the FD&C Act?

Information about each device approval, including its review time, appears in this report at Appendix A. "FDA Review Days" are the number of days FDA reviewed the document, not counting time periods where an application was on hold waiting on additional information requested from the sponsor. "Total Review Days" is a running count from the filing date through the approval date.

IV. Conclusion

The information contained in this year's report provides information and an initial accounting with respect to the approval of devices that may be used in pediatric patients, as required by section 515A of the FD&C Act. The report also summarizes FDA's activities prior to the effective date of this new statutory provision to promote the development of pediatric devices.

History Page

Prepared by: Phil Chao: OCD:1/27/09
Edited by: Nicole Wolanski:ODE:2/4/09
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Sent to FDA Exec Sec:2/26/09
Wanda Russ:HF-40 rec'd report on 3/2/09.
G://Wp/WANDAR/FDAA 302 Report to Congress 2008 Ped Devices 3-2-09 Revised OES 2009-1205.doc
Reviewed and cleared with edits by Wanda Russ:HF-40:3/2/09
To Julie Frandsen:HF-40:3/2/09 for review and clearance.
Cleared by Julie Frandsen:HF-40:3/2/09 w/minor edits.
To Dotty Foellmer:HF-40:3/2/09 at 4:15 p.m. for r/c.
Returned with edits on 3/4/09.
Revised and returned to Dotty Foellmer:HF-40:3/5/09.
Cleared by Dotty Foellmer:HF-40 on 3/6/09.
Sent to E-Room on 3/6/09 to Vicki Babb for r/c.
Cleared by Vicki Babb on 3/6/09.
Sent in Orange Folder to Susan Winckler on 3/10 for r/c.
Returned to CDRH for revision per Susan Winckler comments 3/12/09.
Revised PDesjardins CDRH 3/12/09 4:30.

Appendix A
Device Approvals and Review Times Report

PMA Device Information	**Indications**[1]
Freestyle Navigator Continuous Glucose Monitor Abbott Labs Number P050020 Filing Date 06/8/05 Approval Date 03/12/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 295 Total Review Days 1008	For continually recording interstitial fluid glucose levels in people (ages 18 and older) with diabetes mellitus for the purpose of improving diabetes management. Readings and alarms about glucose levels from the freestyle navigator continuous glucose monitoring system are not intended to replace traditional blood glucose monitoring.
Cobas Taqman HBV Test Roche Molecular Systems Number P050028 Filing Date 08/02/05 Approval Date 09/04/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 316 Total Review Days 1129	For use with the cobas taqman hbv test with the high pure system, an in vitro nucleic acid amplification test for the quantification of hepatitis b virus (hbv) DNA in human serum or plasma, using the high pure viral nucleic acid kit for manual specimen preparation and the cobas taqman 48 analyzer for automated amplification and detection to aid in the management of patients with chronic hbv infection undergoing anti-viral therapy.
Spot-light HER2 Cish Kit Invitrogen Corporation Number P050040 Filing Date 11/03/05 Approval Date 07/01/08 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 314 Total Review Days 971	To quantitatively determine her2 gene amplification in formalin-fixed, paraffin-embedded breast carcinoma tissue sections using chromogenic in situ hybridization and brightfield microscopy. This test should be performed in a histopathology laboratory as an aid in the assessment of patients for whom herceptin (trastuzumab) treatment is being considered.

[1] Although the disease or condition that the device treats, diagnoses or cures may exist in pediatric populations, most of the devices listed in the table are not specifically intended or labeled for pediatric use.

PMA Device Information	**Indications**
Dako TOP2A Fish Pharmdx Kit Dako Denmark Number P050045 Filing Date 11/30/05 Approval Date 01/11/08 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 319 Total Review Days 772	To detect amplifications and deletions (copy number changes) of the top2a gene using fluorescence in situ hybridization (fish) technique on formalin-fixed, paraffin-embedded human breast cancer tissue specimens. Deletions and amplifications of the top2a gene serve as a marker for poor prognosis in high-risk breast cancer patients. Results from the top2a fish pharmdx kit are intended for use as an adjunct to existing clinical and pathological information.
Akreos Posterior Chamber IOL Baush & Lomb Number P060022 Filing Date 08/13/06 Approval Date 09/05/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 631 Total Review Days 754	For the visual correction of aphakia in adult patients where a cataractous lens has been removed by phacoemulsification. The lens is intended to be placed in the capsular bag.
Ovatio CRT System ELA Medical Number P060027 Filing Date 11/17/05 Approval Date 05/15/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 334 Total Review Days 545	For ventricular antitachycardia pacing and ventricular defibrillation for automated treatment of life threatening arrhythmias. The device is also indicated for the reduction of heart failure of symptoms in medically optimized nyha functional class iii and iv patients with left ventricular ejection fraction of 35% or less, and a qrs duration of 150 ms or longer Situs over the wire left ventricular lead is designed to pace the left ventricle through a coronary vein. It is intended to be used in conjunction with ela medical cardiac synchronization therapy pulse generators.

PMA Device Information	**Indications**
Endeavor Zotarolimus Eluting Coronary Stent System Medtronic Number P060033 Filing Date 11/20/06 Approval Date 02/01/08 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 224 Total Review Days 438	For improving coronary luminal diameter in patients with ischemic heart disease due to de novo lesions of length <=27 mm in native coronary arteries with reference vessel diameters of >=2.5 mm to <=3.5 mm.
Architect Core-M Reagent Abbott Laboratories Number P060035 Filing Date 12/01/06 Approval Date 11/06/07 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? Yes Exempt From User Fees? No FDA Review Days 179 Total Review Days 340	For the qualitative detection of igm antibody to hepatitis b core entigen (igm anti-hbc) in human adult and pedric serum or plasma (dipotassium edta, lithium heparin, and sodium heparin) and neonatal serum. A test for igm anti-hbc is indicated as an aid in the diagnosis of acute or recent hepatitis b virus (hbv) infection in conjunction with other laboratory results and clinical information.
Nexgen LPS Flex Mobile and LPS-Mobile Bearing Knee System Zimmer, Inc. Number P060037 Filing Date 12/18/06 Approval Date 12/10/07 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 320 Total Review Days 357	For patients with severe knee pain and disability due to osteoarthritis; primary and secondary traumatic arthritis; avascular necrosis of the femoral condyle; or moderate valgus, varus, or flexion deformities (i.e., valbus/varus deformity of, =15 degrees, fixed flexion deformity of <=10 degrees). This device is intended for cemented use only.

PMA Device Information	**Indications**
Mitroflow Aortic Pericardial Heart Valve Carbomedics Number P060038 Filing Date 12/18/06 Approval Date 10/23/07 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 248 Total Review Days 309	For the replacement of diseased, damaged, or malfunctioning native or prosthetic aortic valves.
Attain Starfix Lead Medtronics Number P060039 Filing Date 12/27/06 Approval Date 06/13/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 419 Total Review Days 534	For chronic pacing and sensing of the left ventricle via the cardiac vein, when used in conjunction with a compatible implantable pulse generator or implantable cardiac defibrillator.
Thoratec Heartmate II Left Ventricular Assist System Thoratec Number P060040 Filing Date 12/22/06 Approval Date 04/21/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 370 Total Review 486	For use as a bridge to transplantation in cardiac transplant candidates at risk of imminent death from non-reversible left ventricular failure. The Heartmate II left ventricular assist system is intended for use both inside and outside the hospital, or for transportation of ventricular assist device patients via ground ambulance, fixed-wing aircraft, or helicopter.

PMA Device Information	**Indications**
Prodisc Total Disc Replacement Synthes Spine Number P070001 Filing Date 01/03/07 Approval Date 12/17/07 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 329 Total Review 348	For reconstruction of the disc from c3-c7 following single-level discectomy for intractable symptomatic cervical disc disease, which is a neck or arm (radicular) pain and/or a functional/neurological deficit with at least one of the following conditions confirmed by imaging (ct, mri, or x-rays): • Herniated nucleus pulposus • Spondylosis (presence of osteophytes) and/or • Loss of disc height.
T-Spot – TB Test Oxford Immunotec, LTD Number P070006 Filing Date 02/06/07 Approval Date 07/30/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? Yes Exempt From User Fees? No FDA Review Days 133 Total Review 540	For the detection of effector t cells that respond to stimulation by mycobacterium tuberculosis antigens esat-6 and cfp-10 by capturing interferon gamma in the vicinity of t cells in human whole blood collected in sodium citrate or sodium or lithium heparin.
Talent Thoracic Stent Graft System Medtronic Vascular Number P070007 Filing Date 07/16/07 Approval Date 06/05/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 221 Total Review Days 325	For the endovascular repair of fusiform aneurysms and saccular aneurysms/penetrating ulcers of the descending thoracic aorta in patients having appropriate anatomy, including: • Iliac/femoral access vessel morphology compatible with vascular access techniques, devices and/or accessories. • Non-aneurysmal aortic diameter in the range of 18-42mm. • Non-aneurysmal aortic proximal and distal neck lengths >=20mm.

PMA Device Information	Indications
Stratos LV CRT-P and Stratos LV-T CRT-P Biotronik, Inc. Number P070008 Filing Date 03/12/07 Approval Date 05/12/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 246 Total Review Days 427	For patients who have moderate to severe heart failure (nyha class ii1/iv), including left ventricular dysfunction (ef<35%) and QRS >120 ms and remain symptomatic despite stable, optimal heart failure drug therapy, intended for permanent implantation in the left ventricle via the coronary veins to provide pacing and/or sensing when used in conjunction with a compatible is-1 pulse generator.
Exponent Self-Expanding Carotid Stent System Medtronic Vascular Number P070012 Filing Date 04/30/07 Approval Date 10/23/07 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 176 Total Review Days 176	For improving carotid luminal diameter using a Medtronic vascular embolic protection system, for improving carotid luminal diameter in patients at high risk for adverse events from carotid endarterectomy who require carotid revascularization and meet certain criteria.
Evolence Collagen Filler Colbar Lifescience LTD (J&J) Number P070013 Filing Date 04/30/07 Approval Date 06/27/08 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 320 Total Review Days 424	Indicated for the correction of moderate to deep facial wrinkles and folds such as nasolabial folds.

PMA Device Information	**Indications**
Xience V Everolimus Eluting Coronary Stent System Abbott Laboratories Number P070015 Filing Date 06/01/07 Approval Date 07/22/08 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 148 Total Review Days 397	For improving coronary luminal diameter in patients with symptomatic heart disease due to de novo native coronary artery lesions (length <=28 mm) with reference vessel diameters of 2.5 mm to 4.25 mm.
Zenith TX2 Thoracic TAA Endovascular Graft Cook Number P070016 Filing Date 07/02/07 Approval Date 05/21/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 179 Total Review Days 324	For the endovascular treatment of patients with aneurysms or ulcers of the descending thoracic aorta having vascular morphology suitable for endovascular repair.
Talent Abdominal Stent Graft System Medtronic Vascular Number P070027 Filing Date 10/18/07 Approval Date 04/15/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 180 Total Review Days 380	For the endovascular treatment of abdominal aortic aneurysms with or without iliac involvement having: • Iliac/femoral access vessel morphology compatible with vascular access techniques, devices, and/or accessories. • Proximal aortic neck length of >=10mm. • Proximal aortic neck angulation <=60. • Distal iliac artery fixation length of >=15mm • Aortic neck diameter of 18-32mm and iliac artery diameters of 8-22mm. • Vessel morphology suitable for endovascular repair.

PMA Device Information	**Indications**
Hoya Ispheric Model YA-60BB IOL Hoya Surgical Optics, Inc. Number P080004 Filing Date 01/31/08 Approval Date 09/26/08 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 178 Total Review Days 239	For primary implantation in the capsular bag of the eye for the visual correction of aphakia in adult patients in whom a cataractous lens has been removed.
Contak Renewal 3 AVT CRT-D System Guidant Corp. Number P010012/S037 Filing Date 11/10/04 Approval Date 03/13/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 735 Total Review Days 1219	For patients with moderate to severe heart failure who remain symptomatic despite stable, optimal heart failure drug therapy and have left ventricular dysfunction (ef <=35%) and qrs duration >=120 ms. Contak renewal 3 AVT provides atrial antitachycardia pacing and atrial defibrillation treatment for patients with a history of or who are at risk of developing atrial arrhythmias.
Taxus Express Pcliataxel-Eluting Coronary Stent System Boston Scientific Corp. Number P030025/S028 Filing Date 04/27/06 Approval Date 09/24/08 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 452 Total Review Days 881	For improving luminal diameter for the treatment of de novo lesions in native coronary arteries >=2.25 to <+4.00mm in diameter in lesions <=28mm in length, and within bare metal stent restenotic lesions >=2.25 to <=3.75mm in diameter and <=28mm in length.

PMA Device Information	**Indications**
SJM Epic Valve and Epic Supra Valve St. Jude Medical, Inc. Number P040021/S004 Filing Date 09/29/06 Approval Date 11/15/07 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 366 Total Review Days 412	For patients requiring replacement of a diseased, damaged, or malfunctioning native aortic and/or mitral heart valve. It may also be used as a replacement for a previously implanted aortic and/or mitral prosthetic heart valve.
Gore Viabahn Endoprosthesis WL Gore & Associates, Inc. Number P040037/S007 Filing Date 11/20/07 Approval Date 08/14/08 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 214 Total Review Days 268	For improving blood flow in patients with symptomatic peripheral arterial disease in iliac artery lesions with reference vessel diameters ranging from 4.0—12.0mm.
Access Hybritech PSA WHO Standardization Beckman Coulter, Inc. Number P850048/S021 Filing Date 08/28/07 Approval Date 05/09/08 Pediatric Subpopulation? No Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 168 Total Review Days 255	For the quantitative determination of total prostate specific antigen (psa) in human serum using the access immunoassay systems. The device is indicated for the measurement of serum psa in conjunction with digital rectal examination as an aid in the detection of prostate cancer in men aged 50 years or older.

HDE Device Information	**Indications**
Epicel Cultured Epidermal Autograph Genzyme Biosurgery Number H990002 Filing Date 02/05/99 Approval Date 10/25/07 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 753 Total Review Days 3267	For use in patients who have deep dermal or full thickness burns comprising a total body surface area >=30%. It may be used in conjunction with split-thickness Autografts, or alone in patients for whom split-thickness Autografts may not be an option due to the severity and extent of their burns.
NeuRX RA/4 Respiratory Stimulation System Synapse Biomedical, Inc. Number H070003 Filing Date 07/18/07 Approval Date 06/17/08 Pediatric Subpopulation? Yes Approved and Labeled for Pediatric Use? No Exempt From User Fees? No FDA Review Days 314 Total Review Days 335	For use in patients with stable, high spinal cord injuries with stimulatable diaphragms, but lack control of their diaphragms. The device is indicated to allow the patients to breathe without the assistance of a mechanical ventilator for at least four continuous hours a day. For use only in patients 18 years of age of older.

Tab B

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 2 1 2009

The Honorable Edward M. Kennedy
Chairman
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Mr. Chairman:

Attached for your consideration is the Food and Drug Administration's Report to Congress regarding the premarket approval of devices that may be used in pediatric patients, as required by section 302 of the Food and Drug Administration Amendments Act (Public Law 110-85), which the President signed into law on September 27, 2007. Section 302, which added new section 515A(a)(3) to the Federal Food, Drug, and Cosmetic Act (the Act), requires FDA to provide an annual report with information concerning premarket approvals of devices that may be used in pediatric patients. This is FDA's first report pursuant to this requirement. The report uses information from FDA's Center for Devices and Radiological Health, and reflects approvals made during fiscal year (FY) 2008.

The report provides background information about the history of FDA's activities to promote the development of safe and effective pediatric devices and to protect the pediatric subpopulations during the course of clinical trials. It then provides the data and information required under section 515A(a)(3) of the Act for approvals made during FY 2008.

In FY 2008, 15 out of 27 premarket approval applications (PMAs) and 2 humanitarian device exemptions were approved for diseases or conditions from which a pediatric subpopulation may suffer. Two of the 15 PMAs were labeled for use in pediatric patients. None of the device applications approved was exempt from user fees because they did not propose conditions of use intended solely for a pediatric population.

I hope you will find the report useful and informative.

Sincerely,

Charles E. Johnson
Acting Secretary

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 2 1 2009

The Honorable Henry A. Waxman
Chairman
Committee on Energy and Commerce
House of Representatives
Washington, DC 20515

Dear Mr. Chairman:

Attached for your consideration is the Food and Drug Administration's Report to Congress regarding the premarket approval of devices that may be used in pediatric patients, as required by section 302 of the Food and Drug Administration Amendments Act (Public Law 110-85), which the President signed into law on September 27, 2007. Section 302, which added new section 515A(a)(3) to the Federal Food, Drug, and Cosmetic Act (the Act), requires FDA to provide an annual report with information concerning premarket approvals of devices that may be used in pediatric patients. This is FDA's first report pursuant to this requirement. The report uses information from FDA's Center for Devices and Radiological Health, and reflects approvals made during fiscal year (FY) 2008.

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Charles E. Johnson
Acting Secretary

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 2 1 2009

The Honorable Nancy Pelosi
Speaker of the House of Representatives
Washington, DC 20515

Dear Madam Speaker:

Attached for your consideration is the Food and Drug Administration's Report to Congress regarding premarket approval of devices that may be used in pediatric patients, as required by section 302 of the Food and Drug Administration Amendments Act (Public Law 110-85), which the President signed into law on September 27, 2007. Section 302, which added new section 515A(a)(3) to the Federal Food, Drug, and Cosmetic Act (the Act), requires FDA to provide an annual report with information concerning premarket approvals of devices that may be used in pediatric patients. This is FDA's first report pursuant to this requirement. The report uses information from FDA's Center for Devices and Radiological Health, and reflects approvals made during fiscal year (FY) 2008.

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Charles E. Johnson
Acting Secretary

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 21 2009

The Honorable Joseph Biden, Jr.
President United States Senate
Washington, DC 20510

Dear Mr. President:

Attached for your consideration is the Food and Drug Administration's Report to Congress regarding the premarket approval of devices that may be used in pediatric patients, as required by section 302 of the Food and Drug Administration Amendments Act (Public Law 110-85), which the President signed into law on September 27, 2007. Section 302, which added new section 515A(a)(3) to the Federal Food, Drug, and Cosmetic Act (the Act), requires FDA to provide an annual report with information concerning premarket approvals of devices that may be used in pediatric patients. This is FDA's first report pursuant to this requirement. The report uses information from FDA's Center for Devices and Radiological Health, and reflects approvals made during fiscal year (FY) 2008.

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Charles E. Johnson
Acting Secretary

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 2 1 2009

The Honorable Joe L. Barton
Ranking Member
Committee on Energy and Commerce
House of Representatives
Washington, DC 20515

Dear Mr. Barton:

Attached for your consideration is the Food and Drug Administration's Report to Congress regarding the premarket approval of devices that may be used in pediatric patients, as required by section 302 of the Food and Drug Administration Amendments Act (Public Law 110-85), which the President signed into law on September 27, 2007. Section 302, which added new section 515A(a)(3) to the Federal Food, Drug, and Cosmetic Act (Act), requires FDA to provide an annual report with information concerning premarket approvals of devices that may be used in pediatric patients. This is FDA's first report pursuant to this requirement. The report uses information from FDA's Center for Devices and Radiological Health, and reflects approvals made during fiscal year (FY) 2008.

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Sincerely,

Charles E. Johnson
Acting Secretary

Enclosure

THE SECRETARY OF HEALTH AND HUMAN SERVICES
WASHINGTON, D.C. 20201

APR 2 1 2009

The Honorable Michael B. Enzi
Ranking Member
Committee on Health, Education, Labor, and Pensions
United States Senate
Washington, DC 20510

Dear Senator Enzi:

Attached for your consideration is the Food and Drug Administration's Report to Congress regarding the premarket approval of devices that may be used in pediatric patients, as required by section 302 of the Food and Drug Administration Amendments Act (Public Law 110-85), which the President signed into law on September 27, 2007. Section 302, which added new section 515A(a)(3) to the Federal Food, Drug, and Cosmetic Act (Act), requires FDA to provide an annual report with information concerning premarket approvals of devices that may be used in pediatric patients. This is FDA's first report pursuant to this requirement. The report uses information from FDA's Center for Devices and Radiological Health, and reflects approvals made during fiscal year (FY) 2008.

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Sincerely,

Charles E. Johnson
Acting Secretary

Enclosure