REPORT TO CONGRESS

Premarket Approval of Pediatric Uses of Devices – FY 2009-2011

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

_/s/_____ Date _____
Margaret A. Hamburg, 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) 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 most recent 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 2009-2011. In addition, this report provides background information about FDA's activities to facilitate the development of safe and effective pediatric devices. This report highlights the following information:

In FY 2009:

- FDA approved 27 original and panel track supplement premarket approval applications (PMAs) and four humanitarian device exemption (HDE) applications.
- Among these approvals, eight PMA devices and no HDE devices were approved for treatment, diagnosis or cure of a disease or condition which occurs within a pediatric subpopulation.
- Two PMA devices were labeled for use in all pediatric patients and six PMA devices were labeled for use in a pediatric subpopulation (adolescents 18 years through 21 years of age).
- No approved device applications were exempt from user fees for proposed conditions of use intended solely for a pediatric population.
- Information about each FY 2009 pediatric device approval, including its review time and the pediatric population for which it is labeled, appears in this report at Appendix A.

In FY 2010:

- FDA approved 19 original and panel track supplement PMAs and one HDE application.
- Seven PMA devices and one HDE application device were approved for treatment, diagnosis or cure of a disease or condition which occurs within a pediatric subpopulation.
- Seven PMA devices and one HDE device were labeled for use in a subset of the pediatric population. All labeled indications were for adolescents; the age boundaries in labeling ranged from 15 years through 21 years of age.
- No approved device application was exempt from user fees for proposed conditions of use intended solely for a pediatric population.
- Information about each FY 2010 pediatric device approval, including its review time and the pediatric population for which it is labeled, appears in this report at Appendix B.

In FY 2011:

- FDA approved 38 original and panel track supplement premarket approval applications (PMAs) and 3 humanitarian device exemption (HDE) applications.
- Among the 41 approvals, 15 PMA devices and 2 HDE devices were approved for treatment, diagnosis or cure of a disease or condition which occurs within a pediatric subpopulation.

- 15 PMA devices were labeled for use in all pediatric patients and 13 PMA devices were labeled for use in a specific pediatric subpopulation (adolescents 18 years through 21 years of age).
- No approved device applications were exempt from user fees because the device is intended solely for pediatric use.
- Information about each FY 2011 pediatric device approval, including its review time and the pediatric population for which it is labeled, appears in this report at Appendix A.

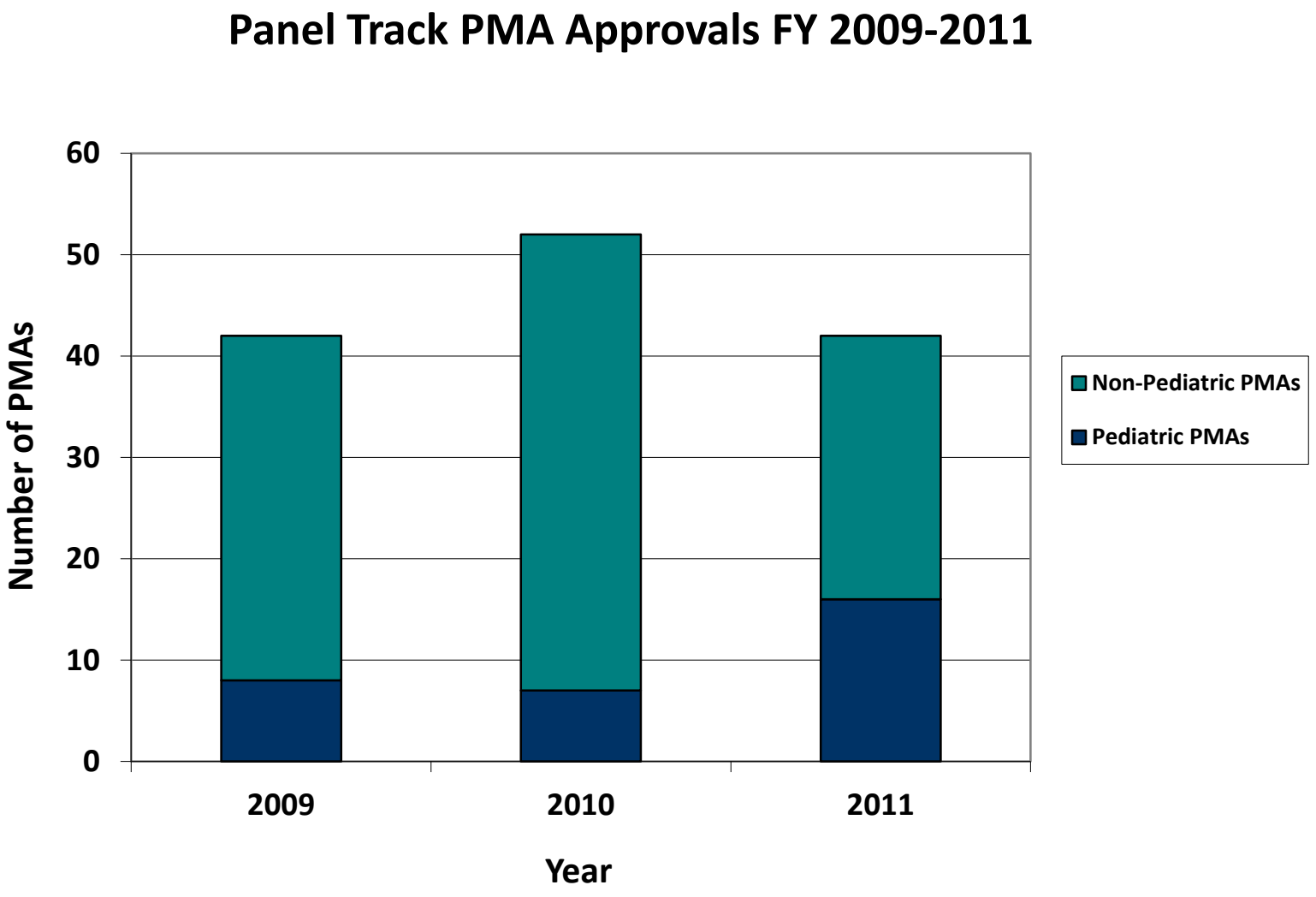

Table of Contents

I. Introduction

In 2007, Congress passed the Food and Drug Administration Amendments Act (FDAAA) (Public Law 110-85), which amended the Food, Drug, and Cosmetic Act (FD&C Act) and added section 515A, "Pediatric Use of Devices." 21 U.S.C. § 360e–1. 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 second report pursuant to section 515A(a)(3) of 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 fiscal years (FY) 2009, 2010, and 2011, as well as background information regarding section 515A of the FD&C Act and our 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]

[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.

This report is intended to highlight what FDA has done in 2011 to foster the development of devices for use in pediatric patients.

A. What Information is Required Under Section 515A(a) of the FD&C Act

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 application) or a product development protocol under section 515 of the FD&C Act[3] to include (if readily available) the following information:

- 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" as one of the following populations:

- Neonates;
- Infants;
- Children; and
- Adolescents.

B. How has FDA Implemented Section 515A(a)

FDA issued a "direct to final" rule and companion proposed rule to implement section 515A(a) of the FD&C Act.[4] Because FDA received significant adverse comment on the direct final rule, the direct final rule was withdrawn[5] and FDA is planning to issue an amended proposed rule that more closely tracks the language and intent of the statute. When finalized, the rule will codify the specific pediatric information that is required from sponsors in particular submissions to FDA, as well as the consequences of not submitting the required information. It will also allow FDA to better track pediatric submissions. FDA also intends to issue a draft guidance to provide recommendations about how manufacturers can comply with the rule.

---

[2] Applications under section 520(m) of the FD&C Act are commonly known as Humanitarian Device Exemption applications (HDEs).
[3] Applications under section 515 of the FD&C Act are commonly known as Premarket Approval Applications (PMAs).
[4] 75 Fed. Reg. 16347, 16365 (April 1, 2010).
[5] 75 Fed. Reg. 41986 (July 20, 2010).

III. Examples of Devices Cleared or Approved for Pediatric Populations

First-of-a-Kind Pediatric Facemask – 510(k)

The Kimberly-Clark Pediatric/Child Facemask, which received clearance on September 23, 2011, was developed to protect pediatric users (5-12 years of age) against airborne particulates, such as respiratory tract bacteria, viruses, and other pathogens, in a health care setting. Since children, particularly those with respiratory infections, do not breathe as forcefully as adults, the face mask is less resistant to airflow than an adult mask. Performance tests reviewed by FDA showed that air flow and filtering ability of the mask were appropriate for children.

ELANA Arteriotomy System

The ELANA (Excimer Laser Assisted Non-Occlusive Anastamosis) Surgical Kit was approved under a Humanitarian Device Exemption on March 10, 2011. This device allows neurosurgeons to reroute blood flow around an aneurysm or a tumor without clamping the intracranial artery in the brains of patients at greater risk of stroke during standard bypass surgery. This device is indicated for creating arteriotomies during an intracranial vascular bypass procedure in patients 13 years of age or older with an aneurysm or a skull base tumor affecting a large [> 2.5 mm] intracranial artery that failed balloon test occlusion, cannot be sacrificed, or cannot be treated with conventional means due to local anatomy or complexity

IV. FDA Implementation of Section 505 of the Pediatric Medical Device Safety and Improvement Act of 2007 (PMDSIA)

Section 505 of PMDSIA (section 305 of FDAAA) establishes demonstration grants for non-profit consortia to facilitate the development, production, approval, and distribution of pediatric medical devices. The Pediatric Device Consortia (PDC) grant program was established within FDA's Office of Orphan Product Development in March of 2009. Since then, a total of $8 million dollars has been awarded to five non-profit consortia. In FY2011, funding was granted to the following four groups (the fifth consortium received a no-cost extension):

- The Michigan - Pediatric Medical Device Institute Pediatric Device Consortium, led by James Geiger, MD and Andre Muelenaer
- The University of California, San Francisco Pediatric Device Consortium, led by Michael Harrison, MD
- The Atlanta Pediatric Device Consortium, led by Barbara Boyan, PhD
- The MISTRAL (Multidisciplinary Initiative for Surgical Technology Research - Advanced Laboratory) Pediatric Device Consortium, led by Pablo Garcia and Sanjeev Dutta, MD

These consortia serve as national resources to advise and assist individuals with pediatric device ideas on how to best proceed with the development of their potential products. The consortia provide guidance and support in areas such as prototyping a device; protecting intellectual property; designing preclinical and clinical trials; and obtaining funding for particular projects utilizing both Federal and non-Federal sources. The consortia also assess potential device

projects for their scientific merit. In addition, the consortia oversee and foster the development of individual device projects.

V. Additional Pediatric Device Development Activities

During 2011, FDA has engaged in a range of additional projects to develop and strengthen its pediatric device development program. These efforts are summarized below.

The ASK CHILDREN Study

The ASK CHILDREN Study, titled "Assess Specific Kinds of CHILDREN Challenges for Neurologic Devices STUDY," is an ongoing study in pediatric patients with cerebral shunts, cochlear implants, deep brain stimulators, vagus nerve stimulators, and implanted bladder systems. More information about this study is available at http://www.fda.gov/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHOffices/ucm300081.htm.

The purpose of this research study is to develop a framework of science-based recommendations to help expedite pediatric prostheses to market, including recommendations for the research and development of neurologic devices. The study goals are as follows:

1. To collect qualitative and quantitative self-report clinical data and identify scientific and medical issues associated with pediatric devices when used in children undergoing treatment; and
2. To establish a science-based framework of recommendations to help develop more efficient strategies for evaluating pediatric products regulated by the Agency.

The IMPACT Registry

In January 2011, the American College of Cardiology (ACC), through its National Cardiovascular Data Registry (NCDR) and with partial funding from FDA, fully launched the IMPACT Registry to collect data on the prevalence, demographics, management and outcomes of pediatric and adult patients with congenital heart disease who are undergoing diagnostic and catheter-based interventions.

FDA has contributed funding to this registry, the only one of its kind and scope, over several years; the current funding allows the ACC NCDR to expand the number of participating sites and assess the feasibility of various mechanisms to obtain longitudinal follow-up on patients in the registry.

Pediatric Advisory Committee (PAC)

The PAC advises and makes recommendations to the Commissioner of Food and Drugs regarding (1) pediatric research conducted under sections 351, 409I, and 499 of the Public Health Service Act and sections 501, 502, 505, 505A, and 505B of the FD&C Act, (2) identification of research priorities related to pediatric therapeutics and the need for additional treatments of specific pediatric diseases or conditions, (3) the ethics, design, and analysis of clinical trials related to pediatric therapeutics, (4) pediatric labeling disputes as specified in section 3 of the

Best Pharmaceuticals for Children Act (BPCA) (Public Law 107-109), (5) pediatric labeling changes as specified in section 5 of the BPCA, (6) adverse event reports for drugs granted-pediatric exclusivity and any safety issues that may occur as specified in section 17 of the BPCA, (7) any other pediatric issue or pediatric labeling dispute involving FDA-regulated products, (8) research involving children as subjects as specified in 21 CFR 50.54, and (9) any other matter involving pediatrics for which FDA has regulatory responsibility.

The PAC held its second meeting on September 22 - 23, 2011. At that time, the PAC reviewed a number of drug and device products, including the Melody® Transcatheter Pulmonary Valve (TPV) and Ensemble Delivery System. CDRH, together with the Office of Pediatric Therapeutics, provided training and detailed presentations to the PAC.

FDA PUBLIC WORKSHOP: Using Scientific Research Data to Support Pediatric Medical Device Claims

On December, 5, 2011, FDA held a public workshop entitled: "Using Scientific Research Data to Support Pediatric Medical Device Claims: A Public Dialogue." The purpose of the public workshop was to receive comments from a variety of stakeholders on the use of scientific research data, including published scientific literature, to extrapolate effectiveness claims from adults to children and between pediatric subpopulations in order to support and establish pediatric indications for medical devices. This workshop supports FDA's efforts to define pathways for approving pediatric device indications by leveraging available scientific research data. Emphasis was placed on determining how and when it is appropriate to use existing scientific research data to establish pediatric effectiveness based on: 1) a similar course of a disease or condition; 2) a similar effect of a device on adults, or; 3) a similar extrapolation between pediatric subpopulations. FDA plans to publish a draft guidance reflecting in part the feedback from the workshop.

Pediatric Communication and Outreach:
Publications

FDA has published three articles related to pediatrics. They are the following:

- "Details Crucial when reporting adverse events due to medical devices. Medical Device Adverse Event Reporting in Pediatrics." American Academy of Pediatrics (AAP) Food and Drug Administration, Office of Pediatric Therapeutics, Pediatric & Maternal Health Staff, and Center for Devices and Radiological Health. AAP NEWS, 2011; 32; 10. Vol 32, No 4. April 2011.
- Federal Pediatric Initiatives on Infant Positioners: Practicing, Promoting, and Supporting a Safe Sleep Environment American Public Health Association (APHA) 10/29/20111-11/02/2011.
- AAP NEWS: FDA UPDATE: "Drop side-rail cribs needed for pediatric patient care in hospitals." AAP NEWS Vol 32, No 8, August 2011.

Baby Products with SIDS Prevention Claims WebPage

On October, 17, 2011, CDRH launched a website titled, "Baby Products with SIDS Prevention Claims," to inform consumers about the risks of these products, provide recommendations for safe baby sleep, and emphasize that FDA has never cleared or approved any device to prevent SIDS. http://www.fda.gov/ForConsumers/ConsumerUpdates/ucm275847.htm

MedSun KidNet

The Medical Product Safety Network (MedSun) is an adverse event reporting program with the primary goal of working collaboratively with the clinical community to identify, understand, and solve problems with the use of medical devices. Over 350 health care facilities, primarily hospitals, participate in the entire MedSun network, which focuses on identifying, understanding, and solving problems with medical devices used in neonatal and other pediatric patients, especially those in intensive care units. Approximately 46 of the 350 MedSun hospitals participate in the KidNet clinical specialty area network within MedSun. Reporting through MedSun's KidNet has increased from 108 reports in 2010 to 153 reports received in 2011.

FDA continues to provide learning opportunities for MedSun KidNet hospitals through presentations via teleconferences and webcasts for healthcare professionals working in neonatal and pediatric patient care areas, focusing on the need to recognize and report device-related problems as part of their patient safety efforts. Additionally, in 2011, FDA increased this education and outreach to KidNet hospitals via telephone and e-mail.

VI. Conclusion

The information contained in this 2011 report provides information and accounting with respect to the approval of devices that are labeled for use in pediatric patients or intended to treat, diagnose, or cure diseases from which pediatric patients suffer for fiscal year 2011, as required by section 515A of the FD&C Act. The report also summarizes FDA's activities to promote the development of pediatric devices. FDA continues to push forward on getting more medical devices approved for pediatrics such as the Melody Transcatheter Pulmonary Valve.

Appendix A
FY 2009 Device Approvals for Pediatric Patients with Review Times[6]

FY 2009	
PMA Device Information	
Helios II Diagnostic Ablation Catheter	
Manufacturer	Stereotaxis, Inc.
Number	P050029
Filing Date	07/03/2006
Approval Date	10/10/2008
Approved, Labeled Pediatric Subpopulation:	18 years and older
Exempt from User Fees?	No
FDA Review Days	452
Total Review Days	830
Repel-CV® Bioresorbable Adhesion Barrier	
Manufacturer	Target Health, Inc.
Number	P070005
Filing Date	01/30/2007
Approval Date	03/06/2009
Approved, Labeled Pediatric Subpopulation:	Birth through 21 years.
Exempt from User Fees?	No
FDA Review Days	275
Total Review Days	766
FC2 Female Condom	
Manufacturer	The Female Health Co.
Number	P080002
Filing Date	01/08/2008
Approval Date	03/10/2009
Approved, Labeled Pediatric Subpopulation:	18 years and older.
Exempt from User Fees?	No
FDA Review Days	279
Total Review Days	427

[6] Any PMA intended solely for pediatric use are exempt from user fees as well as HDEs.

PMA Device Information	
Cervista HPV 16/18—HPV Type 16 and type 18 DNA detection Kit	
Manufacturer	Third Wave Technologies, Inc.
Number	P080015
Filing Date	04/28/2008
Approval Date	03/12/2009
Approved, Labeled Pediatric Subpopulation:	18 years and older
Exempt from User Fees?	No
FDA Review Days	176
Total Review Days	313
ARCHITECT® CORE Reagent Kit, ARCHITECT® CORE Calibrator and ARCHITECT® CORE Controls —Kit to detect antibody to HBV core antigen	
Manufacturer	Abbott Laboratories
Number	P080023
Filing Date	08/28/2008
Approval Date	04/10/2009
Approved, Labeled Pediatric Subpopulation:	All ages
Exempt from User Fees?	No
FDA Review Days	179
Total Review Days	225
Adiana Permanent Contraception System—Contraceptive tubal occlusion device and delivery system	
Manufacturer	Hologic, Inc.
Number	P070022
Filing Date	08/10/2007
Approval Date	07/06/2009
Approved, Labeled Pediatric Subpopulation:	18 years and older
Exempt from User Fees?	No
FDA Review Days	319
Total Review Days	697
DuraSeal Spine Sealant System—Surgical sealant system	
Manufacturer	Confluent Surgical, Inc.
Number	P080013
Filing Date	04/25/2008
Approval Date	09/04/2009
Approved, Labeled Pediatric Subpopulation:	18 years and older
Exempt from User Fees?	No
FDA Review Days	430
Total Review Days	497

Appendix B
FY 2010 Device Approvals for Pediatric Patients with Review Times

FY 2010	
PMA Device Information	
Esteem Implantable Hearing System—Implantable Middle Ear Hearing Device	
Manufacturer	Envoy Medical Corporation
Number	P090018
Filing Date	08/04/2009
Approval Date	03/17/2010
Approved, Labeled Pediatric Subpopulation:	18 years and older
Exempt from User Fees?	No
FDA Review Days	220
Total Review Days	225
Alair Bronchial Thermoplasty System	
Manufacturer	Asthmatx, Inc.
Number	P080032
Filing Date	12/30/2008
Approval Date	04/27/2011
Approved, Labeled Pediatric Subpopulation:	18 years and older
Exempt from User Fees?	No
FDA Review Days	414
Total Review Days	483
Elecsys® Anti-HCV Immunoassay and Elecsys® PreciControl Anti-HCV for use on the Cobas e 411 Immunoassay Analyzer	
Manufacturer	Roche Diagnostics Corporation
Number	P090007
Filing Date	05/15/2009
Approval Date	04/29/2010
Approved, Labeled Pediatric Subpopulation:	21 years and older
Exempt from User Fees?	No
FDA Review Days	178
Total Review Days	349

PMA Device Information	
Elecsys® Anti-HCV Immunoassay and Elecsys® PreciControl Anti-HCV for use on the MODULAR ANALYTICS E170 Analyzer	
Manufacturer	Roche Diagnostics Corporation
Number	P090009
Filing Date	05/15/2009
Approval Date	04/29/2010
Approved, Labeled Pediatric Subpopulation:	21 years and older
Exempt from User Fees?	No
FDA Review Days	178
Total Review Days	349
OraQuick HCV Rapid Antibody Test and Control Kit	
Manufacturer	OraSure Technologies, Inc.
Number	P080027
Filing Date	09/24/2008
Approval Date	06/25/2010
Approved, Labeled Pediatric Subpopulation:	15 years and older
Exempt from User Fees?	No
FDA Review Days	54
Total Review Days	609
Abbott Real Time HBV Assay assay for use with the Abbott *m*2000 System DNA reagents and with the Abbott *m*200*sp* and *m*2OOO*rt* instruments	
Manufacturer	Abbott Laboratories
Number	P080026
Filing Date	10/16/2008
Approval Date	08/13/2010
Approved, Labeled Pediatric Subpopulation:	16 years and older
Exempt from User Fees?	No
FDA Review Days	170
Total Review Days	666
HDE Device Information	
Melody Transcatheter Pulmonary Valve (Model PB10) and Medtronic Ensemble Transcatheter Valve and Delivery System (NU10)	
Manufacturer	Medtronic, Inc.
Number	H080002
Filing Date	08/28/2008
Approval Date	01/25/2010
Approved, Labeled Pediatric Subpopulation:	All pediatric age groups
Exempt from user fees because intended solely for pediatric use? (note HDEs are statutorily exempt from user fees)	No
FDA Review Days	374
Total Review Days	514

Appendix C
FY 2011 Device Approvals for Pediatric Patients with Review Times

FY 2011	
PMA Device Information	
Lap-Band	
Manufacturer	Allergan, Inc.
Number	P000008/S017
Filing Date	4/27/2010
Approval Date	2/16/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees?	No
FDA Review Days	295
Total Review Days2	95
HER2 Fish Pharmdx Kit	
Manufacturer	Dako Denmark A/S
Number	P040005/S005
Filing Date	4/20/2010
Approval Date	10/20/2010
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees?	No
FDA Review Days	82
Total Review Days	183
RX Acculink Carotid Stent System	
Manufacturer	Abbott Vascular Inc.
Number	P040012/S034
Filing Date	10/1/2010
Approval Date	5/6/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees?	No
FDA Review Days	217
Total Review Days	217
Ceramax Ceramic Hip System	
Manufacturer	DePuy, Inc.
Number	P070026
Filing Date	10/1/2007
Approval Date	12/23/2010
Approved, Labeled Pediatric Subpopulation:	Skeletally Mature
Exempt from User Fees?	No
FDA Review Days	900
Total Review Days	1179

PMA Device Information	
Medtronic Interstim Sacral Nerve Therapy System	
Manufacturer	Medtronic Inc.
Number	P080025
Filing Date	9/26/2008
Approval Date	3/14/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees?	No
FDA Review Days	180
Total Review Days	899
Oraquick HCV Rapid Antibody Test	
Manufacturer	Orasure Technologies, Inc.
Number	P080027/S001
Filing Date	8/30/2010
Approval Date	2/18/2011
Approved, Labeled Pediatric Subpopulation:	15 and older
Exempt from User Fees?	No
FDA Review Days	172
Total Review Days	172
Vitros Immunodiagnostic Products HBEAG Reagent Pack/ Products HBEAG Calibrator /Product HBE Controls	
Manufacturer	Ortho-Clinical Diagnostics, Inc.
Number	P090028
Filing Date	12/17/2009
Approval Date	5/11/2011
Approved, Labeled Pediatric Subpopulation:	2 - adult
Exempt from User Fees?	No
FDA Review Days	148
Total Review Days	510
Vitros Immunodiagnostic Products Anti-HBE/ Anti-HBE Calibrator/ Anti-HBE Controls	
Manufacturer	Ortho-Clinical Diagnostics, Inc.
Number	P100001
Filing Date	1/29/2010
Approval Date	7/20/2011
Approved, Labeled Pediatric Subpopulation:	2 - adult
Exempt from User Fees?	No
FDA Review Days	175
Total Review Days	537

Abbott Realtime HCV, Abbott Realtime HCV Amplification Reagent kit, Abbott Realtime HVC Control Kit, Abbott Realtime HCV	
Manufacturer	Abbott Molecular Inc.
Number	P100017
Filing Date	5/18/2010
Approval Date	5/17/2011
Approved, Labeled Pediatric Subpopulation:	No age limits imposed
Exempt from User Fees?	No
FDA Review Days	146
Total Review Days	364
Medtronic Vascular Endurant Stent Graft System	
Manufacturer	Medtronic Vascular
Number	P100021
Filing Date	6/4/2010
Approval Date	12/16/2010
Approved, Labeled Pediatric Subpopulation:	18 years and older
Exempt from User Fees?	No
FDA Review Days	175
Total Review Days	195
Valiant Thoracic Stent Graft System	
Manufacturer	Medtronic Vascular
Number	P100040
Filing Date	10/8/2010
Approval Date	4/1/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees?	No
FDA Review Days	175
Total Review Days	175
Propel	
Manufacturer	Intersectent
Number	P100044
Filing Date	12/6/2010
Approval Date	8/11/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees?	No
FDA Review Days	178
Total Review Days	248

PMA Device Information	
RX Herculink Elite Renal Stent System	
Manufacturer	Abbott Vascular
Number	P110001
Filing Date	1/3/2011
Approval Date	7/20/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees?	No
FDA Review Days	178
Total Review Days	198
Legoo	
Manufacturer	Pluromed, Inc.
Number	P110003
Filing Date	1/31/2011
Approval Date	9/28/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees?	No
FDA Review Days	180
Total Review Days	240
Cobra 4800 BRAF V600 Mutation Test	
Manufacturer	Roche Molecular Systems Inc.
Number	P110020
Filing Date	4/25/2011
Approval Date	8/17/2011
Approved, Labeled Pediatric Subpopulation:	18 and older
Exempt from User Fees?	No
FDA Review Days	93
Total Review Days	114

HDE Device Information	
Elana Surgical Kit	
Manufacturer	Elana, Inc.
Number	H080005
Filing Date	12/5/2008
Approval Date	3/10/2011
Approved, Labeled Pediatric Subpopulation:	13 yrs or older
Exempt from User Fees because intended solely for pediatric use? (note HDEs are statutorily exempt from user fees)	No
FDA Review Days	519
Total Review Days	825

NeuRx DPS™ Diaphragm Pacing System	
Manufacturer	Synapse Biomedical, Inc.
Number	H100006
Filing Date	10/12/2010
Approval Date	9/28/2011
Approved, Labeled Pediatric Subpopulation:	21 yrs or older
Exempt from User Fees because intended solely for pediatric use? (note HDEs are statutorily exempt from user fees)	No
FDA Review Days	305
Total Review Days	970