2014 - 2015 Strategic Priorities

Strike the Right Balance Between Premarket and Postmarket Data Collection

Goal: Assure the appropriate balance between premarket and postmarket data collection to facilitate and expedite the development and review of medical devices, in particular high-risk devices of public health importance.

Target

By December 31, 2015, review 100 percent of product codes subject to a PMA that have been on the market to determine whether or not to shift some premarket data collection to the postmarket setting or to pursue reclassification, and communicate those decisions to the public.

Results

In 2014 and 2015, CDRH reviewed 100 percent of product codes subject to a PMA that have been on the market.

In April 2015, FDA announced that as of December 31, 2014, CDRH reviewed 69 percent of the product codes included in this retrospective review and published the results of the analysis for these product codes online at http://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHVisionandMission/UCM444804.pdf. Table 1 and Table 2 below provide remaining product codes that were reviewed during 2015 that are candidates for reclassification, a reduction in premarket data collection through reliance on postmarket controls, or a shift in premarket data collection to postmarket collection. The product codes in these tables are additive to those previously reported.

Table 1. Medical devices (by product code) determined to be candidates for reclassification to Class II.

Product Code (PROCODE)	PROCODE Description
LGW	Stimulator, Spinal-Cord, Totally Implanted For Pain Relief
LLQ	Cap, Cervical, Contraceptive
LPA	System, Esophageal Pacing
LPG	Material, Dressing, Surgical, Polylactic Acid
MAD	Catheter, Percutaneous (Valvuloplasty)
MHY	Stimulator, Electrical, Implanted, For Parkinsonian Tremor
MTV	Device, Needle Destruction
NBN	Generator, Shock-Wave, For Pain Relief
NHL	Stimulator, Electrical, Implanted, For Parkinsonian Symptoms
NIO	Stent, Iliac
OCK	Transurethral Occlusion Insert, Urinary Incontinence-Control, Female

Table 2. Medical devices (by product code) determined to be candidates for reduction of premarket data collection through reliance on postmarket controls or shift of data collection from premarket to postmarket.

Product Code (PROCODE)	PROCODE Description	Proposed Change or Shift
FAF	Prosthesis, Testicular	FDA is considering reducing postmarket follow-up times for saline-filled devices, since the successfully completed postapproval study for this device subtype demonstrates that it is rare for significant problems to occur beyond 3 years.
MEQ	System, Hyperthermia, Rf/Microwave (Benign Prostatic Hyperplasia),Thermotherapy	FDA is considering eliminating postapproval studies, since the successfully completed postapproval studies did not raise long-term safety concerns and treatment durability is consistent throughout the studies.
MLV	Transcatheter Septal Occluder	FDA is considering reducing premarket clinical data collection for atrial septal defect (ASD) occluders through the use randomized control trials against approved ASD occluders rather than a randomized control trial against surgical repair. FDA will rely on postmarket controls to verify that the safety and effectiveness of use of the device is maintained long term.
MMY	Lipoprotein, Low Density, Removal	FDA is considering reducing the duration of post approval studies, because the postapproval studies for this device type showed no significant changes in device safety or effectiveness after 5 years.
MNB	Device, Thermal Ablation, Endometrial	FDA has developed Objective Performance Criteria (OPC) to streamline clinical trials for this device type. FDA will rely on postmarket controls to verify that the safety and effectiveness of use of the device is maintained long term.
NRZ	Ablation System, High Intensity Focused Ultrasound (HIFU), MR-Guided	FDA is considering reducing premarket clinical study requirements to single-arm study rather than a controlled study against hysterectomy. FDA will rely on postmarket controls to verify that the safety and effectiveness of the device is maintained long term.

Table 3. Medical devices (by product code) with reduction or shift in data collection and/or reclassification in 2015, during FDA's retrospective review of PMAs.

Product Code (PROCODE)	PROCODE Description	Description of FDA Action
LTF	Stimulator, Salivary System	Reclassification to Class II, special controls, completed November 20, 2015.
MGB	Device, Hemostasis, Vascular	Reductions in premarket data collections have been implemented in 2015. FDA previously required randomized controlled clinical trials comparing the vascular closure device to manual compression. This collection of clinical data has been reduced to single arm studies with performance goals for comparison and reliance on postmarket controls.
MJP	Toric IOL	Shifts in some clinical data requirements from premarket to postmarket setting have been implemented in the past year. FDA previously required premarket clinical data for the submission of a PMA supplement to add a higher cylinder power lens (i.e., higher astigmatic correction) to an already approved toric IOL platform. This collection of clinical data has been shifted to the postmarket setting.
MKQ	Processor, cervical cytology slide, automated	Reductions in premarket data collections have been implemented in 2015. FDA is collecting additional data on severe abnormal cases through post-approval studies, in order to reduce potentially very large premarket studies, to ensure effectiveness of the device in rare, but severe abnormal cells in cervical cytology cases.
MNM	Reader, cervical cytology slide, automated	Reductions in premarket data collections have been implemented in 2015. FDA is collecting additional data on severe abnormal cases through post-approval studies, in order to reduce potentially very large premarket studies, to ensure effectiveness of the device in rare, but severe abnormal cells in cervical cytology cases.

Table 4. Additional medical devices (by product code) determined to remain class III with no changes in data collection.

Product Code (PROCODE)	PROCODE Description
DSQ	Ventricular (Assist) Bypass
EZW	Stimulator, Electrical, Implantable, For Incontinence
EZY	Device, Incontinence, Mechanical/Hydraulic
GZE	Implanted Diaphragmatic/Phrenic Nerve Stimulator
HEO	Analyzer, Data, Obstetric
HHS	Insert, Tubal Occlusion
HPX	Lens, Contact (Polymethylmethacrylate)
HQL	Intraocular Lens
KNH	Device, Occlusion, Tubal, Contraceptive, Laparoscopic
KRG	Programmer, Pacemaker
LKN	Separator, Automated, Blood Cell And Plasma, Therapeutic
LMH	Implant, Dermal, For Aesthetic Use
LNM	Agent, Bulking, Injectable For Gastro-Urology Use
LOE	Stimulator, Invasive Bone Growth
LOG	Catheter, Balloon For Retinal Reattachment
LOZ	Artificial Heart
LPB	Cardiac Ablation Percutaneous Catheter
LPC	Device, Angioplasty, Laser, Coronary
LPM	Lenses, Soft Contact, Extended Wear
LQE	Implant, Corneal, Refractive
LSZ	Ventilator, High Frequency
LZD	Joint, Temporomandibular, Implant
LZP	Aid, Surgical, Viscoelastic
MAE	Occluder, patent ductus, arteriosus
MAF	Stent, Coronary
MCN	Barrier, Absorable, Adhesion
MCX	Catheter, Coronary, Atherectomy
MDD	Device, Dermal Replacement
MFA	Device, Removal, Pacemaker Electrode, Percutaneous
MGR	Dressing, Wound And Burn, Interactive
MIR	Shunt, Portosystemic, Endoprosthesis
MOA	Analyzer, Diagnostic, Fiber Optic (Colon)
MOU	Intravascular Radiation Delivery System
MOZ	Acid, Hyaluronic, Intraarticular
MPI	Glenoid Fossa Prosthesis
MRJ	Ring, Endocapsular
MTE	System, Pacing, Temporary, Acute, Internal Atrial Defibrillation
MUQ	Glue, Surgical, Arteries
MVK	Wearable Automated External Defibrillator
MWD	Electrosurgical, Radio Frequency, Refractive Correction
NBE	Sealant, Polymerizing
NCJ	Telescope, Implantable, Miniature
NEG	Finger Semi-Constrained Pyrolytic Carbon Uncemented Prosthesis

NIQ	Coronary Drug-Eluting Stent
NPZ	Bone Grafting Material, Dental, With Biologic Component
NRA	Prosthesis, Knee, Femorotibial, Unicompartmental, Semi-Constrained, Metal/Polymer, Mobile Bearing
NTG	Prosthesis, Ankle, Uncemented, Non-Constrained
OAE	Catheter, Percutaneous, Cardiac Ablation, For Treatment Of Atrial Fibrillation
OBD	Barrier, Adhesion, Cardiovascular
OGO	Intraocular Pressure Lowering Implant
OOY	Bronchial Thermoplasty System
OSR	Pacemaker/ICD/CRT Non-Implanted Components