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, 2014, review 50 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, CDRH reviewed 69 percent of product codes subject to a PMA that have been on the market.

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

Product Code (PROCODE)	PROCODE Description
LFD	Saliva, artificial
LLX	Catheter, sampling, chorionic villus
LMF	Agent, absorbable hemostatic, collagen based
LNC	Applicator, hyperthermia, superficial, rf/microwave
LOA	Device, testicular hypothermia
LOB	Dilator, cervical, synthetic osmotic
LOC	System, rf/microwave hyperthermia, cancer treatment
LOF	Bone growth stimulator
LPQ	Stimulator, ultrasound and muscle, for use other than applying therapeutic deep
LTF	Stimulator, salivary system
LZR	Ultrasound, cyclodestructive
MBU	Condom, female, single-use
MRK	System, imaging, fluorescence
MVF	System, laser, photodynamic therapy
MVG	System, laser, fiber optic, photodynamic therapy
MYL	Assay, enzyme linked immunosorbent, parvovirus b19 igg
MYM	Assay, enzyme linked immunosorbent, parvovirus b19 igm
MYN	Analyzer, medical image
NXG	Fluorescence in situ hybridization, topoisomerase ii alpha, gene amplification and deletion
NZC	Stent, urethral, prostatic, semi-permanent
OAY	Light source system, diagnostic endoscopic

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
FHW	Device, impotence , mechanical/hydraulic	Significantly reduce premarket and postmarket follow-up times. FDA is considering approximately a 50% reduction in both cases. FDA is also considering eliminating certain endpoints, including the connective tissue disease (CTD) endpoint. This is based on current clinical experience which shows that the majority of adverse events and revision surgeries occurred within a more acute timeframe following device implantation than initially expected. FDA will rely on postmarket controls to verify that the safety and effectiveness of use of the device is maintained long term.
FTR	Prosthesis, breast, noninflatable, internal, silicone gel-filled	FDA is considering changing clinical data requirements from a single-arm study with a large number of patients to a controlled study with pre-specified endpoints and potentially fewer patients.
FWM	Prosthesis, breast, inflatable, internal, saline	FDA is considering changing clinical data requirements from a single-arm study with a large number of patients to a controlled study with pre-specified endpoints and potentially fewer patients.
JCW	Prosthesis, penis, inflatable	Significantly reduce premarket and postmarket follow-up times. FDA is considering approximately a 50% reduction in both cases. FDA is also considering eliminating certain endpoints, including the connective tissue disease (CTD) endpoint. This is based on current clinical experience which shows that the majority of adverse events and revision surgeries occurred within a more acute timeframe following device implantation than initially expected. FDA will rely on postmarket controls to verify that the safety and effectiveness of use of the device is maintained long term.
LOK	Kit, test, alpha-fetoprotein for neural tube defects	FDA is considering requiring performance standards or non-clinical tests that have been developed as potential surrogates for some of the clinical testing. Since there is enough experience with these devices, FDA is considering that objective criteria can eliminate the need for controlled studies.
MJP	Toric IOL	Issues for higher cylinder power (i.e., higher myopes) related to visual distortions have been previously documented in other PMAs. For the approval to add a higher cylinder power lens to an already approved toric IOL platform, FDA is considering allowing a shift from premarket to postmarket for some clinical data requirements.
MKQ	Processor, cervical cytology slide, automated	FDA is considering collecting additional data on severe abnormal cases post-market, in order to reduce a potentially very large premarket study, but to ensure effectiveness of the device in rare, but severe abnormal cells in cervical cytology

Product Code (PROCODE)	PROCODE Description	Proposed Change or Shift
		cases.
MNM	Reader, cervical cytology slide, automated	FDA is considering collecting additional data on severe abnormal cases post-market, in order to reduce a potentially very large premarket study, but to ensure effectiveness of the device in rare, but severe abnormal cells in cervical cytology cases.
MTF	Total, prostate specific antigen (noncomplexed & complexed) for detection of prostate cancer	FDA is considering requiring performance standards or non-clinical tests that have been developed as potential surrogates for some of the clinical testing.
MTG	Test, prostate specific antigen, free, (noncomplexed) to distinguish prostate cancer from benign conditions	FDA is considering requiring performance standards or non-clinical tests that have been developed as potential surrogates for some of the clinical testing.
MVC	System, test, her-2/neu, ihc	FDA is considering clinical trial data to demonstrate that the test can select a patient population to demonstrate the clinical benefits of the drug may not be necessary for premarket approval for the same intended use. Instead, FDA will rely on postmarket controls to verify the demonstration of patient population selection and benefits for the same intended use.
MVD	System, test, her-2/neu, nucleic acid or serum	FDA is considering clinical trial data to demonstrate that the test can select a patient population to demonstrate the clinical benefits of the drug may not be necessary for premarket approval for new intended use. Instead, FDA will rely on postmarket controls to verify the demonstration of patient population selection and benefits for the same intended use.
NAF	Antigen (complexed), prostate specific, (cpsa)	FDA is considering requiring performance standards or non-clinical tests that have been developed as potential surrogates for some of the clinical testing.
NAW	Microspheres radionuclide	FDA is considering shifting clinical testing for potential indications for use to a post market requirement or to be completed via meta-analysis. FDA is also considering that extensive dosimetry (radiation physics) data or composition of matter type discussions may not be required for premarket approval for some potential expanded indications for use, if the microspheres remain the same.
NKF	Immunohistochemistry antibody assay, c-kit	FDA is considering that clinical trial data to demonstrate that the test can select a patient population to demonstrate the clinical benefits of the drug may not be required for premarket approval for the same intended use. Instead, FDA will rely on postmarket controls to verify the demonstration of patient population selection and benefits for the same intended use.
NQF	Immunohistochemistry assay,	FDA is considering that clinical trial data to demonstrate that

Product Code (PROCODE)	PROCODE Description	Proposed Change or Shift
	antibody, epidermal growth factor receptor	the test can select a patient population to demonstrate the clinical benefits of the drug may not be required for premarket approval for the same intended use. Instead, FDA will rely on postmarket controls to verify the demonstration of patient population selection and benefits for the same intended use.
NYQ	Chromogenic in situ hybridization, nucleic acid amplification, her2/neu gene, breast cancer	FDA is considering that clinical trial data to demonstrate that the test can select a patient population to demonstrate the clinical benefits of the drug may not be required for premarket approval for the same intended use. Instead, FDA will rely on postmarket controls to verify the demonstration of patient population selection and benefits for the same intended use.
OAD	Catheter, percutaneous, cardiac ablation, for treatment of atrial flutter	FDA is considering developing Objective Performance Criteria (OPC) to streamline clinical trials for this device type.
OWD	Somatic gene mutation detection system	FDA is considering collecting clinical trial data post-market to support claims of new or rare variants.
OWE	Fluorescence in situ hybridization, anaplastic lymphoma kinase, gene rearrangement	FDA is considering that clinical trial data to demonstrate that the test can select a patient population to demonstrate the clinical benefits of the drug may not be required for premarket approval for the same intended use. Instead, FDA will rely on postmarket controls to verify the demonstration of patient population selection and benefits for the same intended use.
OYM	Prostate cancer genes nucleic acid amplification test system	FDA is considering that the study sample size required for premarket approval may be reduced by prescreening to enrich for abnormal cases that are of greater interest.

Table 3. Medical devices (by product code) with reduction or shift in data collection and/or reclassification in 2014, during FDA's retrospective review of PMAs.

Product Code (PROCODE)	PROCODE Description	Description of FDA Action
IMK	Wheelchair, stair climbing	Reclassification to Class II, special controls, completed April 14, 2014.
MIH	System, endovascular graft, aortic aneurysm treatment	Reductions in premarket data collections have been implemented in the past year. FDA previously required 1 year of premarket data collection for the submission of a PMA supplement for next generation abdominal and thoracic aortic devices. This requirement has been reduced to 6 months premarket data collection with a minimum of 1 year postmarket data collection for certain types of device modifications. Previously, FDA also allowed a shift from surgical controls to use of clinically relevant performance goals to evaluate effectiveness of abdominal and thoracic aortic devices.
MWA	System, nucleic acid amplification, mycobacterium tuberculosis complex	Reclassification to Class II, special controls, completed May 30, 2014

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

Product Code (PROCODE)	PROCODE Description
DTB	Permanent pacemaker Electrode (870.3680)
DXY	Implantable, pacemaker, pulse-generator
DYE	Replacement heart valve
GZC	Stimulator, neuromuscular, implanted
KGG	Tissue adhesive for use in embolization of brain arteriovenous malformations
KWG	Prosthesis, finger, constrained, metal/polymer
LGB	Gonococcal antibody tests
LHE	Controller, closed-loop blood glucose
LKK	Pump, infusion, implanted, programmable
LKV	Fetal fibronectin
LMG	Agent, absorbable hemostatic, non-collagen based
LMW	Solution, removal, carries
LMX	Meter, Jaundice
LMY	Monitor, skin resistance/skin temperature, for insulin reactions
LNB	Applicator, hyperthermia, deep heating, ultrasound
LNR	System, photopheresis, extracorporeal
LNY	Catheter, percutaneous, long term, intraspinal
LOM	Test, hepatitis b (b core, be antigen, be antibody, b core igm)
LOY	Cardioconverter, implantable
LPD	System, pacing, antitachycardia
LSX	Controller, closed-loop, blood-pressure
LTI	Implant, Intragastric for morbid obesity
LWL	Fluid, intraocular
LWO	Pulse-generator, single chamber, sensor-driver, implanatable
LWP	Implantable, pulse-generator, pacemaker (non-CRT)
LWQ	Heart valve, mechanical
LWR	Heart valve non allograft tissue
LWS	Implantable cardioverter defibrillator (non-CRT)
LWT	Occluder, balloon, vena-cava
LWW	Pulse-generator, single chamber, single
LWY	Pulse-generator, dual chamber, antitachycardia
LXA	Tissue graft of 6,mm or greater
LYJ	Stimulator, autonomic nerve, implanted for epilepsy
LZS	Excimer laser system
MAQ	Kit, DNA detection, human papillomavirus
MCM	Cochlear implant
MDS	Invasive glucose sensor
MER	Stent, urethral, prostatic, permanent or semi-permanent
MES	Stent, urethral, bulbous, permanent or semi-permanent
MFE	Agent, injectable, embolic
MFK	Lens, multifocal intraocular
MHE	Auditory brainstem implant
MHR	Test, antitumor cell susceptibility

MIP	Implanted fecal incontinence device
MJB	Antigen, cancer 549
MJO	Prosthesis, intervertebral disc
MJS	Contrast media, ultrasound
MKD	Stimulator, functional walking neuromuscular, non-invasive
MKT	Hepatitis viral b DNA detection
MNO	System, laser, transmyocardial revascularization
MPV	Implant, hearing, active, middle ear, partially implanted
MPW	Filler, recombinant human bone morphogenetic protein, collagen scaffold, osteoinduction
MRA	Prosthesis, hip, semi-constrained, metal/ceramic/ceramic/metal, cemented or uncemented
MRM	Defibrillator, implantable, dual-chamber
MTA	Lens, intraocular, phakic
MUZ	Stimulator, Autonomic nerve, implanted (depression)
MWH	Pulmonic valved conduit
MWL	Rigid Gas Permeable contact lenses
MXM	Cap, cooling (infants)
MXQ	Stent, urethral, external sphincter, permanent
MZO	Assay, enzyme linked immunosorbent, hepatitis c virus
MZP	Assay, hybridization and/or nucleic acid amplification for detection of hepatitis c RNA, hepatitis c virus
NAA	Lens, intraocular, accommodative
NAH	System, test, tumor marker, for detection of bladder cancer
NCD	Test, immunity, cell mediated, mycobacterium tuberculosis;
NCL	Imager, breast, electrical impedance
NEK	Filler, recombinant human bone morphogenetic protein, collagen scaffold with metal prosthesis, osteoinduction
NIK	Defibrillator, automatic implantable cardioverter, with cardiac resynchronization
NIM	Stent, carotid
NIN	Stent, renal
NIP	Stent, superficial femoral artery
NJL	Total mobile bearing knees
NKE	Pulse-generator, pacemaker, implantable, with cardiac resynchronization (CRT-P)
NQA	Biologic material, dental
NQO	Prosthesis, spinous process spacer/plate
NQR	Sealant, dural
NRM	Pulse generator, dual chamber, ventricular rescue shock, implantable
NUU	Temporary reduction of myopia or refractive error
NVN	Drug eluting permanent right ventricular (RV) or right atrial (RA) pacemaker electrodes
NVY	Permanent defibrillator electrodes
NVZ	Pulse-generator, permanent, implantable
NWX	Catheter, percutaneous transluminal coronary angioplasty (ptca), cutting/scoring
NXT	Prosthesis, hip, semi-constrained, metal/metal, resurfacing
OAF	Implant, hearing, active, middle ear, totally implanted
OBF	ASSAY, GENOTYPING, HEPATITIS C VIRUS;{Export only}
OCB	RT-PCR multigene expression test, sentinel lymph node, cancer metastasis detection
OJN	Mycobacterium tuberculosis, cell mediated immune response, enzyme-linked

	immunospot test
OJX	Drug eluting permanent left ventricular (LV) pacemaker electrode
OTE	Digital breast tomosynthesis
OYA	P2psa
OYB	Kit, RNA detection, human papillomavirus
OYC	Invasive glucose sensor w insulin pump
OZA	Test, urea adult and pediatric (breath)
PAA	Automated breast ultrasound
PAB	Cytomegalovirus (cmv) DNA quantitative assay
PEJ	Salivary estriol test