

**List of Medical Devices, by Product Code,  
that FDA classifies as Implantable, Life-Saving, and Life-Sustaining Devices  
for purposes of Section 614 of FDASIA  
amending Section 519(f) of the FDC Act November 2012**

Product Code - Preferred Name	Device Regulatory Class	Life Saving or Sustaining Devices	Implantable Devices
BSK - CUFF, TRACHEAL TUBE, INFLATABLE	2	Y	N
BSZ - GAS-MACHINE, ANESTHESIA	2	Y	N
BTL - VENTILATOR, EMERGENCY, POWERED (RESUSCITATOR)	2	Y	N
BTM - VENTILATOR, EMERGENCY, MANUAL (RESUSCITATOR)	2	Y	N
BTO - TUBE, TRACHEOSTOMY (W/WO CONNECTOR)	2	Y	N
BTR - TUBE, TRACHEAL (W/WO CONNECTOR)	2	Y	N
BTS - TUBE, BRONCHIAL (W/WO CONNECTOR)	2	Y	N
BWC - NEEDLE, EMERGENCY AIRWAY	2	Y	N
BYE - ATTACHMENT, BREATHING, POSITIVE END EXPIRATORY PRESSURE	2	Y	N
BYK - TENT, OXYGEN, ELECTRICALLY POWERED	2	Y	N
BYT - VENTILATOR, EXTERNAL BODY, NEGATIVE PRESSURE, ADULT (CUIRASS)	2	Y	N
BZR - MIXER, BREATHING GASES, ANESTHESIA INHALATION	2	Y	N
CAC - APPARATUS, AUTOTRANSFUSION	2	Y	N
CAG - CIRCULATOR, BREATHING-CIRCUIT	2	Y	N
CAO - AIRWAY, ESOPHAGEAL (OBTURATOR)	2	Y	N
CAW - GENERATOR, OXYGEN, PORTABLE	2	Y	N
CBF - CHAMBER, HYPERBARIC	2	Y	N
CBI - TUBE, TRACHEAL/BRONCHIAL, DIFFERENTIAL VENTILATION (W/WO CONNECTOR)	2	Y	N
CBK - VENTILATOR, CONTINUOUS, FACILITY USE	2	Y	N
CBO - ATTACHMENT, INTERMITTANT MANDATORY VENTILATION (IMV)	2	Y	N
CBP - VALVE, NON-REBREATHING	2	Y	N

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CCO - BED, ROCKING, BREATHING ASSIST	2	Y	N
DRO - PACEMAKER, CARDIAC, EXTERNAL TRANSCUTANEOUS (NON-INVASIVE)	2	Y	N
DSS - CLIP, VASCULAR	2	N	Y
DST - CLIP, VENA-CAVA	2	N	Y
DSW - BAG, POLYMERIC MESH, PACEMAKER	1	N	Y
DSY - PROSTHESIS, VASCULAR GRAFT, OF 6MM AND GREATER DIAMETER	2	N	Y
DTD - PACEMAKER LEAD ADAPTOR	2	N	Y
DTK - FILTER, INTRAVASCULAR, CARDIOVASCULAR	2	N	Y
DTM - FILTER, BLOOD, CARDIOPULMONARY BYPASS, ARTERIAL LINE	2	Y	N
DTP - DEFOAMER, CARDIOPULMONARY BYPASS	2	Y	N
DTQ - CONSOLE, HEART-LUNG MACHINE, CARDIOPULMONARY BYPASS	2	Y	N
DTR - HEAT-EXCHANGER, CARDIOPULMONARY BYPASS	2	Y	N
DTX - GAS CONTROL UNIT, CARDIOPULMONARY BYPASS	2	Y	N
DTZ - OXYGENATOR, CARDIOPULMONARY BYPASS	2	Y	N
DWA - CONTROL, PUMP SPEED, CARDIOPULMONARY BYPASS	2	Y	N
DWB - PUMP, BLOOD, CARDIOPULMONARY BYPASS, ROLLER TYPE	2	Y	N
DWC - CONTROLLER, TEMPERATURE, CARDIOPULMONARY BYPASS	2	Y	N
DXZ - PATCH, PLEDGET AND INTRACARDIAC, PETP, PTFE, POLYPROPYLENE	2	N	Y
DYF - PROSTHESIS, VASCULAR GRAFT, OF LESS THEN 6MM DIAMETER	2	N	Y
DYX - LOCK, WIRE, AND LIGATURE, INTRAORAL	2	N	Y

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DZE - IMPLANT, ENDOSSEOUS, ROOT-FORM	2	N	Y
DZK - WIRE, FIXATION, INTRAOSSEOUS	2	N	Y
DZL - SCREW, FIXATION, INTRAOSSEOUS	2	N	Y
ELE - IMPLANT, SUBPERIOSTEAL	2	N	Y
ESF - POLYMER, COMPOSITE SYNTHETIC PTFE WITH CARBON-FIBER, ENT	2	N	Y
ESH - POLYMER, ENT SYNTHETIC-PIFE, SILICON ELASTOMER, POLYETHYLENE, POLYURETHANE	2	N	Y
ESW - PROSTHESIS, ESOPHAGEAL	2	N	Y
ESX - TACK, SACCULOTOMY (CODY TACK)	2	N	Y
ESY - PROSTHESIS, OTOPLASTY	2	N	Y
ESZ - TUBE, SHUNT, ENDOLYMPHATIC	2	N	Y
ETA - REPLACEMENT, OSSICULAR PROSTHESIS, TOTAL	2	N	Y
ETB - PROSTHESIS, PARTIAL OSSICULAR REPLACEMENT	2	N	Y
ETC - MOLD, MIDDLE-EAR	2	N	Y
ETD - TUBE, TYMPANOSTOMY	2	N	Y
EZX - MESH, SURGICAL, METAL	2	N	Y
FAD - STENT, URETERAL	2	N	Y
FAE - PROSTHESIS, PENILE	2	N	Y
FEZ - CATHETER AND TUBE, SUPRAPUBIC	2	N	Y
FGE - CATHETER, BILIARY, DIAGNOSTIC	2	Y	Y
FHS - DIALYZER, SINGLE COIL	2	Y	N
FIB - PROTECTOR, TRANSDUCER, DIALYSIS	2	Y	N
FID - TUBING, DIALYSATE	2	Y	N
FIF - SET, DIALYSIS, SINGLE NEEDLE WITH UNI-DIRECTIONAL PUMP	2	Y	N
FIG - CLAMP, TUBING, BLOOD, AUTOMATIC	2	Y	N
FIH - PUMP, INFUSION OR SYRINGE, EXTRA-LUMINAL	2	Y	N
FII - SYSTEM, DIALYSATE DELIVERY, SEALED	2	Y	N

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FIJ - SYSTEM, DIALYSATE DELIVERY, RECIRCULATING, SINGLE PASS	2	Y	N
FIK - SYSTEM, DIALYSATE DELIVERY, RECIRCULATING	2	Y	N
FIL - SYSTEM, DIALYSATE DELIVERY, SINGLE PASS	2	Y	N
FIR - PUMP, BLOOD, EXTRA-LUMINAL	2	Y	N
FIS - FLOWMETER, DIALYSATE	2	Y	N
FIW - ALARM, PILLOW PRESSURE	2	Y	N
FIZ - METER, CONDUCTIVITY, NON-REMOTE	2	Y	N
FJB - DETECTOR, DIALYSATE LEVEL	2	Y	N
FJC - DETECTOR, BLOOD LEVEL	2	Y	N
FJD - DETECTOR, LEAK, BLOOD	2	Y	N
FJF - DETECTOR, AIR BUBBLE	2	Y	N
FJG - DIALYZER, PARALLEL FLOW	2	Y	N
FJH - DIALYZER, DISPOSABLE	2	Y	N
FJI - DIALYZER, CAPILLARY, HOLLOW FIBER	2	Y	N
FJJ - DIALYZER, TWIN COIL	2	Y	N
FJK - SET, TUBING, BLOOD, WITH AND WITHOUT ANTI-REGURGITATION VALVE	2	Y	N
FJS - CATHETER, PERITONEAL, LONG-TERM INDWELLING	2	N	Y
FJT - INTRACATHETER, DIALYSIS	2	Y	N
FKB - CONNECTOR, BLOOD TUBING, INFUSION T	2	Y	N
FKC - CLAMP, CANNULA	1	N	Y
FKD - CANISTER, COIL	2	Y	N
FKJ - FILTER, BLOOD, DIALYSIS	2	Y	N
FKL - INSERT, PUMP, BLOOD	2	Y	N
FKN - ADAPTOR, SHUNT	2	N	Y
FKO - CATHETER, PERITONEAL DIALYSIS, SINGLE USE	2	Y	N
FKP - SYSTEM, DIALYSATE DELIVERY, SINGLE PATIENT	2	Y	N
FKQ - SYSTEM, DIALYSATE DELIVERY, CENTRAL MULTIPLE PATIENT	2	Y	N
FKR - SUBSYSTEM, PROPORTIONING	2	Y	N

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FKT - SYSTEM, DIALYSATE DELIVERY, SORBENT REGENERATED	2	Y	N
FKX - SYSTEM, PERITONEAL, AUTOMATIC DELIVERY	2	Y	N
FKY - CONNECTOR, TUBING, DIALYSATE	2	Y	N
FLA - MONITOR, TEMPERATURE, DIALYSIS	2	Y	N
FLC - STATION, DIALYSIS CONTROL, NEGATIVE PRESSURE TYPE	2	Y	N
FLS - MONITOR, APNEA, FACILITY USE	2	Y	N
FTL - MESH, SURGICAL, POLYMERIC	2	N	Y
FTM - MESH, SURGICAL	2	N	Y
FTQ - PROSTHESIS, PENIS, RIGID ROD	2	N	Y
FWP - PROSTHESIS, CHIN, INTERNAL	2	N	Y
FZD - PROSTHESIS, EAR, INTERNAL	2	N	Y
FZE - PROSTHESIS, NOSE, INTERNAL	2	N	Y
FZP - CLIP, IMPLANTABLE	2	N	Y
GAK - SUTURE, ABSORBABLE	2	N	Y
GAL - SUTURE, ABSORBABLE, NATURAL	2	N	Y
GAM - SUTURE, ABSORBABLE, SYNTHETIC, POLYGLYCOLIC ACID	2	N	Y
GAN - SUTURE, ABSORBABLE, SYNTHETIC	2	N	Y
GAO - SUTURE, NONABSORBABLE	Unclassified	N	Y
GAP - SUTURE, NONABSORBABLE, SILK	2	N	Y
GAQ - SUTURE, NONABSORBABLE, STEEL, MONOFILAMENT AND MULTIFILAMENT, STERILE	2	N	Y
GAR - SUTURE, NONABSORBABLE, SYNTHETIC, POLYAMIDE	2	N	Y
GAS - SUTURE, NONABSORBABLE, SYNTHETIC, POLYESTER	2	N	Y
GAT - SUTURE, NONABSORBABLE, SYNTHETIC, POLYETHYLENE	2	N	Y

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GAW - SUTURE, NONABSORBABLE, SYNTHETIC, POLYPROPYLENE	2	N	Y
GDW - STAPLE, IMPLANTABLE	2	N	Y
GWO - PLATE, CRANIOPLASTY, PREFORMED, ALTERABLE	2	N	Y
GXN - PLATE, CRANIOPLASTY, PREFORMED, NON-ALTERABLE	2	N	Y
GXO - STRIP, CRANIOSYNOSTOSIS, PREFORMED	2	N	Y
GXP - METHYL METHACRYLATE FOR CRANIOPLASTY	2	N	Y
GXQ - DURA SUBSTITUTE	2	N	Y
GXR - COVER, BURR HOLE	2	N	Y
GZB - STIMULATOR, SPINAL-CORD, IMPLANTED (PAIN RELIEF)	2	N	Y
GZF - STIMULATOR, PERIPHERAL NERVE, IMPLANTED (PAIN RELIEF)	2	N	Y
HBP - CLIP, IMPLANTED MALLEABLE	2	N	Y
HBW - FASTENER, PLATE, CRANIOPLASTY	2	N	Y
HCE - CLAMP, CAROTID ARTERY	2	N	Y
HCG - DEVICE, NEUROVASCULAR EMBOLIZATION	2	N	Y
HCH - CLIP, ANEURYSM	2	N	Y
HFJ - PROSTHESIS, FALLOPIAN TUBE	2	N	Y
HPZ - IMPLANT, EYE SPHERE	2	N	Y
HQJ - IMPLANT, ABSORBABLE, (SCLERAL BUCKLING METHODS)	2	N	Y
HQM - KERATOPROSTHESIS, PERMANENT IMPLANT	2	N	Y
HQT - SHELL, SCLERAL	2	N	Y
HQW - CLIP, TANTALUM, OPHTHALMIC	2	N	Y
HQX - IMPLANT, ORBITAL, EXTRA-OCULAR	2	N	Y
HRS - PLATE, FIXATION, BONE	2	N	Y
HRY - PROSTHESIS, KNEE, FEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER	2	N	Y

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HSB - ROD, FIXATION, INTRAMEDULLARY AND ACCESSORIES	2	N	Y
HSD - PROSTHESIS, SHOULDER, HEMI-, HUMERAL, METALLIC UNCEMENTED	2	N	Y
HSH - PROSTHESIS, KNEE, HEMI-, TIBIAL, RESURFACING (UNCEMENTED)	2	N	Y
HSN - PROSTHESIS, ANKLE, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER	2	N	Y
HSX - PROSTHESIS, KNEE, FEMOROTIBIAL, NON-CONSTRAINED, CEMENTED, METAL/POLYMER	2	N	Y
HTG - PROSTHESIS, KNEE, HEMI-, PATELLAR RESURFACING, UNCEMENTED	2	N	Y
HTN - WASHER, BOLT NUT	2	N	Y
HTY - PIN, FIXATION, SMOOTH	2	N	Y
HWC - SCREW, FIXATION, BONE	2	N	Y
HXA - PROSTHESIS, TENDON, PASSIVE	2	N	Y
IWG - SEED, ISOTOPE, GOLD, TITANIUM, PLATINUM	2	N	Y
JAZ - PROSTHESIS, FACIAL, MANDIBULAR IMPLANT	2	N	Y
JCQ - PROSTHESIS, ESOPHAGUS	2	N	Y
JCS - PROSTHESIS, MAXILLA	Unclassified	N	Y
JCT - PROSTHESIS, TRACHEAL, EXPANDABLE	2	N	Y
JDB - PROSTHESIS, ELBOW, SEMI-CONSTRAINED, CEMENTED	2	N	Y
JDC - PROSTHESIS, ELBOW, CONSTRAINED, CEMENTED	2	N	Y
JDD - PROSTHESIS, UPPER FEMORAL	2	N	Y
JDG - PROSTHESIS, HIP, FEMORAL COMPONENT, CEMENTED, METAL	2	N	Y
JDH - PROSTHESIS, HIP, HEMI-, TRUNNION-BEARING, FEMORAL, METAL/POLYACETAL	Not Classified	N	Y
JDI - PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, CEMENTED	2	N	Y

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JDJ - MESH, SURGICAL, ACETABULAR, HIP, PROSTHESIS	2	N	Y
JDK - PROSTHESIS, HIP, CEMENT RESTRICTOR	2	N	Y
JDN - IMPLANT, FIXATION DEVICE, SPINAL	2	N	Y
JDO - DEVICE, FIXATION, PROXIMAL FEMORAL, IMPLANT	2	N	Y
JDP - CONDYLAR PLATE FIXATION IMPLANT	2	N	Y
JDQ - CERCLAGE, FIXATION	2	N	Y
JDR - STAPLE, FIXATION, BONE	2	N	Y
JDS - NAIL, FIXATION, BONE	2	N	Y
JDT - CAP, BONE	1	N	Y
JDW - PIN, FIXATION, THREADED	2	N	Y
JEC - COMPONENT, TRACTION, INVASIVE	2	N	Y
JEY - PLATE, BONE	2	N	Y
JOF - POLYMER, ENT SYNTHETIC, POROUS POLYETHYLENE	2	N	Y
JOH - TUBE TRACHEOSTOMY AND TUBE CUFF	2	Y	N
JOQ - GENERATOR, PULSE, PACEMAKER, EXTERNAL PROGRAMMABLE	2	Y	N
JWH - PROSTHESIS, KNEE, PATELLOFEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED, POLYMER/METAL/POLYMER	2	N	Y
JWI - PROSTHESIS, WRIST, 2 PART METAL-PLASTIC ARTICULATION, SEMI-CONSTRAINED	2	N	Y
JWJ - PROSTHESIS, WRIST, 3 PART METAL-PLASTIC-METAL ARTICULATION, SEMI-CONSTRAINED	2	N	Y
JXG - SHUNT, CENTRAL NERVOUS SYSTEM AND COMPONENTS	2	N	Y
JXH - METHYL METHACRYLATE FOR ANEURYSMORRHAPHY	2	N	Y
JXI - CUFF, NERVE	2	N	Y
KDA - PROSTHESIS, PTFE/CARBON-FIBER	2	N	Y
KDI - DIALYZER, HIGH PERMEABILITY WITH OR WITHOUT SEALED DIALYSATE SYSTEM	2	Y	N



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KDJ - SET, ADMINISTRATION, FOR PERITONEAL DIALYSIS, DISPOSABLE	2	Y	N
KHJ - POLYMER, ENT SYNTHETIC-POLYAMIDE (MESH OR FOIL MATERIAL)	2	N	Y
KHK - POLYMER, ENT NATURAL-COLLAGEN MATERIAL	Unclassified	N	Y
KIG - PROSTHESIS, WRIST, CONSTRAINED, POLYMER	2	N	Y
KKY - MATERIAL, POLYTETRAFLUOROETHYLENE VITREOUS CARBON, FOR MAXILLOFACIAL RECONSTRUCTION	2	N	Y
KLZ - TUBE, SHUNT, ENDOLYMPHATIC WITH VALVE	2	N	Y
KMB - PROSTHESIS, KNEE, NON-CONSTRAINED (METAL-CARBON REINFORCED POLYETHYLENE) CEMENTED	2	N	Y
KMC - PROSTHESIS, HIP, SEMI-CONSTRAINED, COMPOSITE/METAL	2	N	Y
KMD - PROSTHESIS, ANKLE, SEMI-CONSTRAINED, CEMENTED, METAL/COMPOSITE	2	N	Y
KNR - ADAPTER, A-V SHUNT OR FISTULA	2	N	Y
KNZ - ACCESSORIES, A-V SHUNT	2	N	Y
KOB - CATHETER, SUPRAPUBIC (AND ACCESSORIES)	2	N	Y
KOC - ACCESSORIES, BLOOD CIRCUIT, HEMODIALYSIS	2	Y	N
KPF - SYSTEM, DIALYSATE DELIVERY, SEMI-AUTOMATIC, PERITONEAL	2	Y	N
KPK - MARKER, OSTIA, AORTO-SAPHENOUS VEIN	2	N	Y
KPM - SHUNT, PERITONEAL	2	N	Y
KPO - DIALYSATE CONCENTRATE FOR HEMODIALYSIS (LIQUID OR POWDER)	2	Y	N
KPP - PERITONEAL DIALYSATE FILTER	2	Y	N

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KQL - TUBE, TYMPANOSTOMY WITH SEMI-PERMEABLE MEMBRANE	2	N	Y
KQQ - TUBING, DIALYSATE (AND CONNECTOR)	2	Y	N
KQR - DETECTOR, AIR OR FOAM	2	Y	N
KRD - DEVICE, VASCULAR, FOR PROMOTING EMBOLIZATION	2	N	Y
KRH - RING, ANNULOPLASTY	2	N	Y
KRO - PROSTHESIS, KNEE, FEMOROTIBIAL, CONSTRAINED, CEMENTED, METAL/POLYMER	2	N	Y
KRQ - PROSTHESIS, KNEE, PATELLO/FEMOROTIBIAL, CONSTRAINED, CEMENTED, POLYMER/METAL/POLYMER	2	N	Y
KRR - PROSTHESIS, KNEE, PATELLO/FEMORAL, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER	2	N	Y
KTT - APPLIANCE, FIXATION, NAIL/BLADE/PLATE COMBINATION, MULTIPLE COMPONENT	2	N	Y
KTW - APPLIANCE, FIXATION, NAIL/BLADE/PLATE COMBINATION, SINGLE COMPONENT	2	N	Y
KTX - PROSTHESIS, KNEE, FEMOROTIBIAL, NON-CONSTRAINED, METAL/COMPOSITE CEMENTED	2	N	Y
KWD - PROSTHESIS, TOE, HEMI-, PHALANGEAL	2	N	Y
KWF - PROSTHESIS, FINGER, POLYMER	2	N	Y
KWH - PROSTHESIS, TOE, CONSTRAINED, POLYMER	2	N	Y
KWI - PROSTHESIS, ELBOW, HEMI-, RADIAL, POLYMER	2	N	Y
KWK - APPLIANCE, NAIL/BLADE/PLATE COMBINATION, SINGLE COMPONENT	2	N	Y
KWL - PROSTHESIS, HIP, HEMI-, FEMORAL, METAL	2	N	Y
KWM - PROSTHESIS, WRIST, SEMI-CONSTRAINED	2	N	Y

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KWN - PROSTHESIS, WRIST, CARPAL LUNATE	2	N	Y
KWO - PROSTHESIS, WRIST, CARPAL SCAPHOID	2	N	Y
KWP - APPLIANCE, FIXATION, SPINAL INTERLAMINAL	2	N	Y
KWQ - APPLIANCE, FIXATION, SPINAL INTERVERTEBRAL BODY	2	N	Y
KWS - PROSTHESIS, SHOULDER, SEMI-CONSTRAINED, METAL/POLYMER CEMENTED	2	N	Y
KWT - PROSTHESIS, SHOULDER, NON-CONSTRAINED, METAL/POLYMER CEMENTED	2	N	Y
KWY - PROSTHESIS, HIP, HEMI-, FEMORAL, METAL/POLYMER, CEMENTED OR UNCEMENTED	2	N	Y
KWZ - PROSTHESIS, HIP, CONSTRAINED, CEMENTED OR UNCEMENTED, METAL/POLYMER	2	N	Y
KXA - PROSTHESIS, HIP, FEMORAL, RESURFACING	2	N	Y
KXE - PROSTHESIS, WRIST, HEMI-, ULNAR	2	N	Y
KXK - SOURCE, BRACHYTHERAPY, RADIONUCLIDE	2	N	Y
KXM - SYSTEM ACCESSORIES, EXTRACORPOREAL	2	Y	N
KYF - IMPLANT, EYE VALVE	2	N	Y
KYI - PROSTHESIS, WRIST, CARPAL TRAPEZIUM	2	N	Y
KYJ - PROSTHESIS, FINGER, CONSTRAINED, POLYMER	2	N	Y
KYK - PROSTHESIS, KNEE, FEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED, METAL/COMPOSITE	2	N	Y
LBL - TUBE, TYMPANOSTOMY, POROUS POLYETHYLENE	2	N	Y
LBM - POROUS POLYETHYLENE OSSICULAR REPLACEMENT	2	N	Y
LBN - REPLACEMENT, TOTAL OSSICULAR, PROSTHESIS, POROUS, POLYETHYLENE	2	N	Y

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LBP - REPLACEMENT, OSSICULAR (STAPES) USING ABSORBABLE GELATIN MATERIAL	2	N	Y
LCJ - EXPANDER, SKIN, INFLATABLE	Unclassified	N	Y
LDD - DC-DEFIBRILLATOR, LOW-ENERGY, (INCLUDING PADDLES)	2	Y	N
LDF - ELECTRODE, PACEMAKER, TEMPORARY	2	Y	N
LEM - HUMAN LYOPHILIZED DURA MATER	2	N	Y
LFB - BUTTON, NASAL SEPTAL	Unclassified	N	Y
LFK - CATHETER, FEMORAL	2	Y	Y
LGE - PROSTHESIS, KNEE, FEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED, TRUNNION-BEARING	2	N	Y
LGK - PROSTHESIS, MAXILLOFACIAL	Not Classified	N	Y
LHG - ELECTRODE, SPINAL EPIDURAL	2	N	Y
LJS - CATHETER, INTRAVASCULAR, THERAPEUTIC, LONG-TERM GREATER THAN 30 DAYS	2	N	Y
LJT - PORT & CATHETER, IMPLANTED, SUBCUTANEOUS, INTRAVASCULAR	2	N	Y
LKG - PORT & CATHETER, IMPLANTED, SUBCUTANEOUS, INTRAVENTRICULAR	Unclassified	N	Y
LLB - SYSTEM, BLOOD, EXTRACORPOREAL AND ACCESSORIES	2	Y	N
LLD - PORT & CATHETER, IMPLANTED, SUBCUTANEOUS, INTRAPERITONEAL	Unclassified	N	Y
LOD - BONE CEMENT	2	N	Y
LPH - PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED	2	N	Y
LPK - BONE GRAFTING MATERIAL, FOR DENTAL BONE REPAIR	2	N	Y
LQS - SPERMATOCELE, ALLOPLASTIC	Unclassified	N	Y

**List of Medical Devices, by Product Code,  
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amending Section 519(f) of the FDC Act November 2012**

Product Code - Preferred Name	Device Regulatory Class	Life Saving or Sustaining Devices	Implantable Devices
LRI - PH METER FOR DIALYSIS HYDROGEN ION CONCENTRATION	2	Y	N
LWJ - PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, UNCEMENTED	2	N	Y
LXT - APPLIANCE, FIXATION, NAIL/BLADE/PLATE COMBINATION, MULTIPLE COMPONENT, METAL COMPOSITE	2	N	Y
LYC - BONE GRAFTING MATERIAL, SYNTHETIC	2	N	Y
LYP - ACCESSORIES, FIXATION, SPINAL INTERLAMINAL	2	N	Y
LYT - FIXATION ACCESSORY	2	N	Y
LZJ - PROSTHESIS, TOE (METATARSOPHALANGEAL), JOINT, METAL/POLYMER, SEMI-CONSTRAINED	Unclassified	N	Y
LZK - IMPLANT, MALAR	Unclassified	N	Y
LZN - CEMENT OBTURATOR	2	N	Y
LZO - PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/CERAMIC/POLYMER, CEMENTED OR NON-POROUS, UNCEMENTED	2	N	Y
LZY - PROSTHESIS, HIP, HEMI-, FEMORAL, METAL BALL	2	N	Y
MAH - HEARING AID, BONE CONDUCTION, IMPLANTED	2	N	Y
MAL - GRAFT, VASCULAR, SYNTHETIC/BIOLOGIC COMPOSITE	2	N	Y
MAX - INTERVERTEBRAL FUSION DEVICE WITH BONE GRAFT, LUMBAR	2	N	Y
MAY - PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/CERAMIC/POLYMER, CEMENTED OR NON-POROUS CEMENTED, OSTEOPHILIC FINISH	2	N	Y
MAZ - PROSTHESIS, HIP, SEMI-CONSTRAINED, METAL/POLYMER, POROUS UNCEMENTED, OSTEOPHILIC FINISH	Not Classified	N	Y
MBB - BONE CEMENT, ANTIBIOTIC	2	N	Y
MBF - PROSTHESIS, SHOULDER, SEMI-CONSTRAINED, METAL/POLYMER, UNCEMENTED	2	N	Y

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MBH - PROSTHESIS, KNEE, PATELLO/FEMOROTIBIAL, SEMI-CONSTRAINED, UNCEMENTED, POROUS, COATED, POLYMER/METAL/POLYMER	2	N	Y
MBI - FASTENER, FIXATION, NONDEGRADABLE, SOFT TISSUE	2	N	Y
MBL - PROSTHESIS, HIP, SEMI-CONSTRAINED, UNCEMENTED, METAL/POLYMER, POROUS	2	N	Y
MBM - PROSTHESIS, HIP, SEMI-CONSTRAINED OR HEMI-, METAL/PTFE COATED/POLYMER, CEMENTED OR UN-CEMENTED	Not Classified	N	Y
MBP - FILLER, BONE VOID, OSTEOINDUCTION (W/O HUMAN GROWTH FACTOR)	2	N	Y
MBV - PROSTHESIS, KNEE, PATELLO/FEMOROTIBIAL, SEMI-CONSTRAINED, UHMWPE, PEGGED, UNCEMENTED, POLYMER/METAL/POLYMER	2	N	Y
MBZ - INSTRUMENT, ELECTROSURGICAL, FIELD FOCUSED	Not Classified	N	Y
MCA - TAPE, SURGICAL, INTERNAL	Unclassified	N	Y
MCH - CLIP, HEMOSTATIC	2	N	Y
MDL - IMPLANT, TRANSMANDIBULAR	2	N	Y
MDO - FIBRILLATOR, AC, INTERNAL	Not Classified	N	Y
MDV - PORT & CATHETER, INFUSION, IMPLANTED, SUBCUTANEOUS, INTRASPINAL	Not Classified	N	Y
MDX - PORT & CATHETER, INFUSION, IMPLANTED, SUBCUTANEOUS, INTRAPERITONEAL	Not Classified	N	Y
MEH - PROSTHESIS, HIP, SEMI-CONSTRAINED, UNCEMENTED, METAL/POLYMER, NON-POROUS, CALICUM-PHOSPHATE	2	N	Y
MEJ - PROSTHESIS, HIP, SEMI-CONSTRAINED, COMPOSITE/POLYMER	Not Classified	N	Y
MFC - CATHETER, OCCLUDING, CARDIOVASCULAR, IMPLANTABLE	Not Classified	N	Y

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MFH - IMPLANT, INTEGRATED TISSUE	Not Classified	N	Y
MHC - PORT, INTRAOSSEOUS, IMPLANTED	2	N	Y
MIB - ELASTOMER, SILICONE BLOCK	2	N	Y
MIC - IMPLANT, MUSCLE, PECTORALIS	Unclassified	N	Y
MIX - SYSTEM, VOCAL CORD MEDIALIZATION	2	N	Y
MJW - PROSTHESIS, SUBTALAR, PLUG, POLYMER	Unclassified	N	Y
MLB - DEVICE, REPEAT ACCESS (ABDOMEN)	Not Classified	N	Y
MLP - KERATOPROSTHESIS, TEMPORARY IMPLANT, SURGICAL USE	2	N	Y
MLW - WARMER, PERITONEAL DIALYSATE	2	Y	N
MMB - HEARING-AID, TYMPANIC MEMBRANE MAGNET	Not Classified	N	Y
MNF - IMPLANT, TEMPORAL	2	N	Y
MNH - ORTHOSIS, SPONDYLOLISTHESIS SPINAL FIXATION	2	N	Y
MNI - ORTHOSIS, SPINAL PEDICLE FIXATION	2	N	Y
MNT - VENTILATOR, CONTINUOUS, MINIMAL VENTILATORY SUPPORT, FACILITY USE	2	Y	N
MNU - STAPLE, ABSORBABLE	2	N	Y
MOO - ORTHOPEDIC IMPLANT MATERIAL	Unclassified	N	Y
MOP - ROTATOR, PROSTHETIC HEART VALVE	Unclassified	Y	Y
MPB - CATHETER, HEMODIALYSIS, NON-IMPLANTED	2	Y	N
MPD - AUXILLARY POWER SUPPLY (AC OR DC) FOR LOW-ENERGY DC-DEFIBRILLATOR	2	Y	N
MPE - AUXILLARY POWER SUPPLY (AC OR DC) FOR EXTERNAL TRANSCUTANEOUS CARDIAC PACEMAKER	2	Y	N
MQN - EXTERNAL MANDIBULAR FIXATOR AND/OR DISTRACTOR	2	N	Y

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MQO - PROSTHETIC DISC NUCLEUS DEVICE	Not Classified	N	Y
MQP - SPINAL VERTEBRAL BODY REPLACEMENT DEVICE	2	N	Y
MQR - STENT, COLONIC, METALIC, EXPANDABLE	2	N	Y
MQS - SYSTEM, HEMODIALYSIS, ACCESS RECIRCULATION MONITORING	2	Y	N
MQU - OCULAR PEG	2	N	Y
MQV - FILLER, BONE VOID, CALCIUM COMPOUND	2	N	Y
MQY - DOWEL, SMALL JOINT, BONE FUSION	Not Classified	N	Y
MRN - APPARATUS, NITRIC OXIDE DELIVERY	2	Y	N
MRO - APPARATUS, NITRIC OXIDE, BACKUP DELIVERY	2	Y	N
MRP - ANALYZER, NITRIC OXIDE	2	Y	N
MRQ - ANALYZER, NITROGEN DIOXIDE	2	Y	N
MRW - SYSTEM, FACET SCREW SPINAL DEVICE	Unclassified	N	Y
MRY - APPLIANCES AND ACCESSORIES, FIXATION, BONE, ABSORBABLE SINGLE/MULTIPLE COMPONENT	Unclassified	N	Y
MSE - HEMODIALYZER, RE-USE, LOW FLUX	2	Y	N
MSF - HEMODIALYZER, RE-USE, HIGH FLUX	2	Y	N
MSK - IMMUNOASSAY FOR BLOOD TACROLIMUS	Not Classified	Y	N
MSX - SYSTEM, NETWORK AND COMMUNICATION, PHYSIOLOGICAL MONITORS	2	Y	N
MTJ - WAX, BONE	Unclassified	N	Y
MTZ - WRAP, IMPLANT, ORBITAL	2	N	Y
MUF - SYSTEM, JOINT RESTORATION, ARTHROSCOPICALLY DIRECTED	Not Classified	N	Y
MUM - STENT, METALLIC, EXPANDABLE, DUODENAL	2	N	Y
MUV - STIMULATOR, VAGUS NERVE, IMPLANTED, TREMOR	Not Classified	N	Y



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amending Section 519(f) of the FDC Act November 2012**

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MUY - STIMULATOR,VAGUS NERVE, IMPLANTED,(COMA AND VEGETATIVE STATE)	Not Classified	N	Y
MVB - FILLER, BONE VOID, MEDICATED	Not Classified	N	Y
MWX - SYSTEM,PROSTATE,MAGNETIC/THERMAL RODS	Not Classified	N	Y
MXC - RECORDER,EVENT,IMPLANTABLE CARDIAC,(WITHOUT ARRHYTHMIA DETECTION)	2	N	Y
MXD - RECORDER,EVENT,IMPLANTABLE CARDIAC,(WITH ARRHYTHMIA DETECTION)	2	N	Y
MXW - SUTURE, SURGICAL, NONABSORBABLE, POLY (VINYLIDENE FLUORIDE)	2	N	Y
MXX - GEL,CAPSULAR CONTRACTURE REDUCTION	Not Classified	N	Y
MYU - ACCESSORY,BARIUM SULFATE,METHYL METHACRYLATE FOR CRANIOPLASTY	2	N	Y
MYV - SCREW,ODONTIOD	Not Classified	N	Y
MZQ - BALLOON,DETACHABLE,FOR NEUROVASCULAR OCCLUSION	2	Y	Y
MZT - DEVICE,HEIMLICH MANEUVER ASSIST	2	Y	N
MZZ - PROSTHESIS, FEMORAL NAIL	Not Classified	N	Y
NAJ - AGENTS,EMBOLIC,FOR TREATMENT OF UTERINE FIBROIDS	2	N	Y
NAP - CARDIAC SUPPORT MESH WRAP	Not Classified	N	Y
NAR - STIMULATOR,PERIPHERAL NERVE,IMPLANTED (PAIN RELIEF,OCCIPITAL HEADACHE)	Not Classified	N	Y
NBF - PROSTHESIS,RETINAL	Not Classified	N	Y
NBI - CATHETER,INTRAVASCULAR,COOLING	Not Classified	N	Y

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NBM - VENTILATOR,AUTOMATIC CONTROLLER,PERCENT OXYGEN	Not Classified	Y	N
NBQ - STIMULATOR,VAGUS NERVE,IMPLANTED,MYOCLONUS	Not Classified	N	Y
NBY - SUTURE, SURGICAL, NONABSORBABLE, EXPANDED, POLYTETRAFLUROETHYLENE	2	N	Y
NCA - CLIP, IMPLANTABLE, FOR CORONARY ARTERY BYPASS GRAFT (CABG)	2	N	Y
NCB - WEIGHTS, EYELID, IMPLANTABLE	Not Classified	N	Y
NCH - STIMULATOR, VAGUS NERVE, IMPLANTED, FOR TREATMENT OF OBESITY	Not Classified	N	Y
NCN - PROSTHESIS, KNEE, JOINT, PATELLOFEMORALTIBIAL, SEMI-CONSTRAINED, CEMENTED, CERAMIC/POLYMER/METAL	Not Classified	N	Y
NDB - STIMULATOR, VAGUS NERVE, IMPLANTED, FOR ANXIETY	Not Classified	N	Y
NDD - CERCLAGE, FIXATION, METALLIC	2	N	Y
NDE - ROD, FIXATION, INTRAMEDULLARY AND ACCESSORIES, METALLIC AND NON-COLLAPSIBLE	2	N	Y
NDF - PLATE, FIXATION, BONE, NON-SPINAL, METALLIC	2	N	Y
NDG - WASHER, BOLT, NUT, NON-SPINAL, METALLIC	2	N	Y
NDH - NAIL, FIXATION, BONE, METALLIC	2	N	Y
NDI - STAPLE, FIXATION, BONE, METALLIC	2	N	Y
NDJ - SCREW, FIXATION, BONE, NON-SPINAL, METALLIC	2	N	Y
NDK - SYSTEM, EXTERNAL FIXATOR (WITH METALLIC INVASIVE COMPONENTS)	2	N	Y
NDL - PIN, FIXATION, SMOOTH, METALLIC	2	N	Y
NDM - PIN, FIXATION, THREADED, METALLIC	2	N	Y
NDN - CEMENT, BONE, VERTEBROPLASTY	2	N	Y

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NEA - CEMENT, EAR, NOSE AND THROAT	2	N	Y
NEH - ANCHOR, FASCIAL	2	N	Y
NEU - MARKER, RADIOGRAPHIC, IMPLANTABLE	2	N	Y
NEW - SUTURE, SURGICAL, ABSORBABLE, POLYDIOXANONE	2	N	Y
NFK - KIT, REPAIR, CATHETER, HEMODIALYSIS	2	Y	N
NFM - EXPANDER, TISSUE, ORBITAL	2	N	Y
NFN - GUIDEWIRE, CORONARY, TOTAL OCCLUSION	Not Classified	Y	N
NGV - SYSTEM, APPENDAGE CLOSURE, LEFT ATRIAL	Not Classified	N	Y
NHA - ABUTMENT, IMPLANT, DENTAL, ENDOSSEOUS	2	N	Y
NHC - CATHETER, VENTRICULAR (CONTAINING ANTIBIOTIC OR ANTIMICROBIAL AGENTS)	2	N	Y
NHK - RESUSCITATOR, MANUAL, NON SELF-INFLATING	2	Y	N
NHR - MATERIAL, IMPLANT, UTERINE, FOR ADHESIOGENIC EFFECT	Unclassified	N	Y
NHW - ELECTRODE, PACING AND CARDIOVERSION, TEMPORARY, EPICARDIAL	2	Y	N
NIE - CATHETER, HEMODIALYSIS, TRIPLE LUMEN, NON-IMPLANTED	2	Y	N
NIX - HEARING AID, AIR CONDUCTION, TRANSCUTANEOUS SYSTEM	2	N	Y
NJA - ACCESSORY, SYSTEM, EXTERNAL FIXATOR, CONTAINING ANTIMICROBIAL AGENT	2	N	Y
NJC - CLIP, VAS DEFERENS	2	N	Y
NJD - PROSTHESIS, KNEE, FEMOROTIBIAL, SEMI-CONSTRAINED, UNICOMPARTMENTAL/UNICONDYLAR, UNCEMENTED, POROUS-COATED, METAL/POLYMER	2	N	Y
NJU - SUTURE, NONABSORBABLE, NITINOL	2	N	Y

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NKG - ORTHOSIS, CERVICAL PEDICLE SCREW SPINAL FIXATION	Unclassified	N	Y
NKH - ORTHOSIS, PEDICLE SCREW SPINAL SYSTEM, SPONDYLOSIS AND FACET DEGENERATION	Not Classified	N	Y
NKL - MOLECULAR ADSORBENT RECIRCULATING SYSTEM (MARS)	Unclassified	Y	N
NKM - MITRAL VALVE REPAIR DEVICES	Not Classified	N	Y
NMA - TUBE, TRACHEAL, REPROCESSED	2	Y	N
NMJ - CLIP, IMPLANTABLE, REPROCESSED	2	N	Y
NOL - REAGENTS, RNA AMPLIFICATION, SARS CORONAVIRUS	Not Classified	Y	N
NOU - CONTINUOUS, VENTILATOR, HOME USE	2	Y	N
NOV - ANCHOR, SUTURE, BONE FIXATION, METALLIC	2	N	Y
NOY - AGENTS, EMBOLIC, FOR TREATMENT OF BENIGN HYPERPLASIA	Not Classified	N	Y
NPF - MONITOR, APNEA, HOME USE	2	Y	N
NPJ - PROSTHESIS, KNEE PATELLOFEMOROTIBIAL, PARTIAL, SEMI-CONSTRAINED, CEMENTED, POLYMER/METAL/POLYMER	2	N	Y
NPK - BARRIER, SYNTHETIC, INTRAORAL	2	N	Y
NPL - BARRIER, ANIMAL SOURCE, INTRAORAL	2	N	Y
NPM - BONE GRAFTING MATERIAL, ANIMAL SOURCE	2	N	Y
NPU - PROSTHESIS, MITRAL VALVE, PERCUTANEOUSLY DELIVERED	Not Classified	Y	Y
NQB - CONFORMER, OPHTHALMIC, BIOLOGICAL TISSUE	2	N	Y
NQH - SENSOR, PRESSURE, ANEURYSM, IMPLANTABLE	2	N	Y

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NQJ - CATHETER, HEMODIALYSIS, NON-IMPLANTED, ULTRAFILTRATION, FOR PERIPHERAL USE	2	Y	N
NQP - POSTERIOR METAL/POLYMER SPINAL SYSTEM, FUSION	2	N	Y
NQW - ORTHOSIS, SPINE, PLATE, LAMINOPLASTY, METAL	2	N	Y
NQY - VENTILATOR, CONTINUOUS, MINIMAL VENTILATORY SUPPORT, HOME USE	2	Y	N
NRO - SURGICAL LIP IMPLANT	Not Classified	N	Y
NRV - IMPLANTABLE RADIO FREQUENCY TRANSPONDER SYSTEM	2	N	Y
NUD - VERTEBROPLASTY COMPOUND, CALCIUM BASED	2	N	Y
NUN - BONE GRAFTING MATERIAL, HUMAN SOURCE	2	N	Y
NVH - SUTURE, KNOT, MECHANICAL	2	N	Y
NVR - INTERVERTEBRAL FUSION DEVICE WITH BONE GRAFT, SOLID-SPHERE, LUMBAR	Unclassified	N	Y
NVU - AGENT, VASCULAR, EMBOLIZATION, DRUG-ELUTING	Not Classified	N	Y
NWA - PROSTHESIS, TRACHEAL, PREFORMED/MOLDED	2	N	Y
NWJ - SUTURE, RECOMBINANT TECHNOLOGY	2	N	Y
NXM - PROSTHESIS, EYELID SPACER/GRAFT, BIOLOGIC	2	N	Y
NXP - STENT, TIBIAL	Not Classified	N	Y
NXW - STENT, TIBIAL, ABSORBABLE	Not Classified	N	Y
NYT - PROSTHESIS, TRACHEAL, EXPANDABLE, POLYMERIC	2	N	Y
NZT - DOSIMETER, IONIZING RADIATION, IMPLANTED	2	N	Y
OAT - IMPLANT, ENDOSSEOUS, ORTHODONTIC	2	N	Y
OBL - CEMENT, BONE, PRE-FORMED, MODULAR, POLYMERIC, VERTEBROPLASTY	2	N	Y

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OBM - CEMENT, BONE, VERTEBROPLASTY, PRE-FORMED, MODULAR	2	N	Y
OBT - PLATE, BONE, GROWTH CONTROL, PEDIATRIC, EPIPHYSIODESIS	2	Y	Y
OCD - STIMULATOR, CERVICAL SPINAL CORD, CEREBRAL VASOSPASM	Not Classified	Y	N
ODE - ENDOSCOPIC SUTURE/PLICATION SYSTEM, GASTROESOPHAGEAL REFLUX DISEASE (GERD)	2	N	Y
ODL - HYPERTENSION-THERAPY ELECTRICAL NERVE STIMULATION SYSTEM	Not Classified	N	Y
ODM - NOCTURNAL DIALYSATE DELIVERY SYSTEM	Not Classified	Y	N
ODO - SORBENT REGENERATED NOCTURNAL DIALYSATE DELIVERY SYSTEM	Not Classified	Y	N
ODP - INTERVERTEBRAL FUSION DEVICE WITH BONE GRAFT, CERVICAL	2	N	Y
ODU - FACIAL IMPLANT	2	N	Y
OEW - TRACKING, SOFT TISSUE, INTRAOPERATIVE	2	Y	N
OHA - HEART VALVE, MORE THAN MINIMALLY MANIPULATED ALLOGRAFT	Unclassified	N	Y
OIS - CALCIUM SALT BONE VOID FILLER, DRILLABLE, NON-SCREW AUGMENTATION	2	N	Y
OIY - PROSTHESIS, KNEE, PATELLOFEMOROTIBIAL, SEMI-CONSTRAINED, CEMENTED, POLYMER + ADDITIVE/METAL/POLYMER + ADDITIVE	2	N	Y
OJB - RESORBABLE SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS - PLATE	2	N	Y
OJM - RESORBABLE SPINAL INTERVERTEBRAL BODY FIXATION ORTHOSIS - MESH	2	N	Y

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OKC - IMPLANTED SUBCUTANEOUS SECUREMENT CATHETER	2	N	Y
OXS - LACRIMAL STENTS AND INTUBATION SETS	Unclassified	N	Y
OLB - DRUG-ELUTING INTERNAL PUDENDAL ARTERY (IPA) AND HYPOGASTRIC ARTERY STENT	Not Classified	N	Y
OLC - SCAFFOLD, PARTIAL MEDIAL MENISCAL DEFECTS EXTENDING INTO THE RED/WHITE ZONE, RESORBABLE BOVINE COLLAGEN	2	N	Y
OLL - SEPTAL STAPLER/ABSORBABLE STAPLES	2	N	Y
OMF - PERCUTANEOUS, IMPLANTED, LONG-TERM INTRAVASCULAR CATHETER ACCESSORY FOR CATHETER POSITION	2	N	Y
OMH - PERICARDIAL PATCH TO FACILITATE REVISION SURGERIES	2	Y	Y
OMR - VESSEL GUARD OR COVER	2	N	Y
OOD - SURGICAL FILM	2	Y	Y
OOM - SUBTALAR JOINT-CROSSING UNCEMENTED SEMI-CONSTRAINED ANKLE PROSTHESIS	Not Classified	N	Y
OPZ - PROSTHESIS, SHOULDER, NON-TRADITIONAL STEM, SEMI-CONSTRAINED, METAL/POLYMER, UNCEMENTED	2	N	Y
OQG - HIP PROSTHESIS, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER, + ADDITIVE, POROUS, UNCEMENTED	2	N	Y
OQH - HIP, SEMI-CONSTRAINED, CEMENTED, METAL/POLYMER + ADDITIVE, CEMENTED	2	N	Y
OQI - HIP, SEMI-CONSTRAINED, CEMENTED, METAL/CERAMIC/POLYMER + ADDITIVE, POROUS UNCEMENTED	2	N	Y
ORY - PRELUDE TONGUE SUSPENSION SYSTEM	2	N	Y
OSH - PEDICLE SCREW SPINAL SYSTEM, ADOLESCENT IDIOPATHIC SCOLIOSIS	2	N	Y

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OSN - SOFTWARE FOR DIAGNOSIS/TREATMENT	2	N	Y
OSO - IN-SITU, POLYMER, BONE FIXATION	Not Classified	N	Y
OST - IN UTERO FETAL TRACHEAL OCCLUSION DEVICE, DETACHABLE BALLOON AND DELIVERY SYSTEM	Not Classified	N	Y
OTD - ENDOVASCULAR SUTURING SYSTEM	2	N	Y
OTM - MESH, SURGICAL, FOR STRESS URINARY INCONTINENCE, MALE	2	N	Y
OTN - MESH, SURGICAL, SYNTHETIC, UROGYNECOLOGIC, FOR STRESS URINARY INCONTINENCE, FEMALE, MULTI-INCISION	2	N	Y
OTO - MESH, SURGICAL, SYNTHETIC, UROGYNECOLOGIC, FOR APICAL VAGINAL AND UTERINE PROLAPSE, TRANSABDOMINALLY PLACED	2	N	Y
OTP - MESH, SURGICAL, SYNTHETIC, UROGYNECOLOGIC, FOR PELVIC ORGAN PROLAPSE, TRANSVAGINALLY PLACED	2	N	Y
OUR - SACROILIAC JOINT FIXATION	2	N	Y
OVD - INTERVERTEBRAL FUSION DEVICE WITH INTEGRATED FIXATION, LUMBAR	2	N	Y
OVE - INTERVERTEBRAL FUSION DEVICE WITH INTEGRATED FIXATION, CERVICAL	2	N	Y
OVZ - PIN, FIXATION, RESORBABLE, HARD TISSUE	2	N	Y
OWI - BONE FIXATION CERCLAGE, SUBLAMINAR	2	N	Y
OWR - MESH, SURGICAL, NON-ABSORBABLE, FACIAL IMPLANTS FOR PLASTIC SURGERY	2	N	Y
OWS - MESH, SURGICAL, COLLAGEN, PLASTICS, FACIAL IMPLANTS	2	N	Y
OWT - MESH, SURGICAL, ABSORBABLE, ABDOMINAL HERNIA	2	N	Y



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Product Code - Preferred Name	Device Regulatory Class	Life Saving or Sustaining Devices	Implantable Devices
OWU - MESH, SURGICAL, NON-ABSORBABLE, DIAPHRAGMATIC HERNIA	2	N	Y
OWV - MESH, SURGICAL, COLLAGEN, DIAPHRAGMATIC HERNIA	2	N	Y
OWW - MESH, SURGICAL, ABSORBABLE, ORTHOPAEDICS, REINFORCEMENT OF TENDON	2	N	Y
OWX - MESH, SURGICAL, NON-ABSORBABLE, ORTHOPAEDICS, REINFORCEMENT OF TENDON	2	N	Y
OWY - MESH, SURGICAL, COLLAGEN, ORTHOPAEDICS, REINFORCEMENT OF TENDON	2	N	Y
OWZ - MESH, SURGICAL, ABSORBABLE, THORACIC, CHEST WALL RECONSTRUCTION	2	N	Y
OXA - MESH, SURGICAL, NON-ABSORBABLE, THORACIC, CHEST WALL RECONSTRUCTION	2	N	Y
OXB - MESH, SURGICAL, COLLAGEN, THORACIC, CHEST WALL RECONSTRUCTION	2	N	Y
OXC - MESH, SURGICAL, ABSORBABLE, STAPLE LINE REINFORCEMENT	2	N	Y
OXD - MESH, SURGICAL, NON-ABSORBABLE, STAPLE LINE REINFORCEMENT	2	N	Y
OXE - MESH, SURGICAL, COLLAGEN, STAPLE LINE REINFORCEMENT	2	N	Y
OXF - MESH, SURGICAL, ABSORBABLE, PLASTIC AND RECONSTRUCTIVE SURGERY	2	N	Y
OXG - MESH, SURGICAL, NON-ABSORBABLE, PLASTIC AND RECONSTRUCTIVE SURGERY	2	N	Y
OXH - MESH, SURGICAL, COLLAGEN, PLASTIC AND RECONSTRUCTIVE SURGERY	2	N	Y
OXI - MESH, SURGICAL, ABSORBABLE, LARGE ABDOMINAL WALL DEFECTS	2	N	Y

**List of Medical Devices, by Product Code,  
that FDA classifies as Implantable, Life-Saving, and Life-Sustaining Devices  
for purposes of Section 614 of FDASIA  
amending Section 519(f) of the FDC Act November 2012**

Product Code - Preferred Name	Device Regulatory Class	Life Saving or Sustaining Devices	Implantable Devices
OXJ - MESH, SURGICAL, NON-ABSORBABLE, LARGE ABDOMINAL WALL DEFECTS	2	N	Y
OXK - MESH, SURGICAL, COLLAGEN, LARGE ABDOMINAL WALL DEFECTS	2	N	Y
OXL - MESH, SURGICAL, ABSORBABLE, ORGAN SUPPORT	2	N	Y
OXM - MESH, SURGICAL, ABSORBABLE, FISTULA	2	N	Y
OXN - MESH, SURGICAL, COLLAGEN, FISTULA	2	N	Y
OYR - FILLER, BONE VOID, RECOMBINANT PLATELET-DERIVED GROWTH FACTOR	Not Classified	Y	Y
OZI - INTERNAL HINGED ELBOW FIXATOR	Not Classified	N	Y
OZS - PRESSURE, FLUID REMOVAL, FASCIOTOMY, INTRACOMPARTMENTAL	Not Classified	Y	N
PAG - MESH, SURGICAL, NON-SYNTHETIC, UROGYNECOLOGIC, FOR STRESS URINARY INCONTINENCE, FEMALE, MULTI-INCISION	2	N	Y
PAH - MESH, SURGICAL, SYNTHETIC, UROGYNECOLOGIC, FOR STRESS URINARY INCONTINENCE, FEMALE, SINGLE-INCISION MINI-SLING	2	N	Y
PAI - MESH, SURGICAL, NON-SYNTHETIC, UROGYNECOLOGIC, FOR PELVIC ORGAN PROLAPSE, TRANSVAGINALLY PLACED	2	N	Y
PAJ - MESH, SURGICAL, NON-SYNTHETIC, UROGYNECOLOGIC, FOR APICAL VAGINAL AND UTERINE PROLAPSE, TRANSABDOMINALLY PLACED	2	N	Y
PAO - PROSTHESIS, SHOULDER, SEMI-CONSTRAINED, METAL/POLYMER + ADDITIVE, CEMENTED	2	N	Y

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Product Code - Preferred Name	Device Regulatory Class	Life Saving or Sustaining Devices	Implantable Devices
PAW - NONABSORBABLE EXPANDED POLYTETRAFLUOROETHYLENE SURGICAL SUTURE FOR CHORDAE TENDINAE REPAIR OR REPLACEMENT	2	Y	Y
PBI - PROSTHESIS, HIP, CONSTRAINED, CEMENTED OR UNCEMENTED, METAL/POLYMER, + ADDITIVE	2	N	Y
PBJ - CRANIAL DISTRACTION SYSTEM	2	Y	Y
PBQ - FIXATION, NON-ABSORBABLE, FOR PELVIC USE	2	N	Y
PBU - BONE VOID FILLER, SYRINGE	Not Classified	N	Y