

## MEDICAL DEVICES AND ARTICLES USED IN PRODUCT MANUFACTURING CONTAINING BISPHENOL-A RELATED MATERIALS

**Product Code:** FDA product code

**Device Classification Name:** per 21 CFR Part 862-892

**Device Class:** Class of device per 21 CFR Part 862-892

**Contact:** Means of contact of the device with the patient (see examples in FR notice):

**direct** (direct contact with tissue, blood, cerebrospinal fluid, skin, mucous membranes)

**indirect** contact, including external communicating devices (blood pathway circuits, blood and parenteral solution administration sets, etc.)

**Patient Population:** Population for which the device is intended—adult, pediatric or both.

Product Code	Classification Name	Class	Contact		Patient population	
			Direct	Indirect	Adult	Pediatric
BRZ	IV Administration Set	II		X	X	X
CAC	Apparatus, autotransfusion	II	X		X	
CBH	Device, fixation, tracheal tube	I	X		X	
CGA	Glucose oxidate, glucose	II		X	X	X
DRC	Trocar	II	X		X	
DRS	Transducer, blood pressure, extravascular	II	X	X	X	X
DSA	Cable, transducer and electrode, patient (including connector)	II	X	X	X	
DSI	Detector and alarm, arrhythmia	II	X		X	
DTK	Filter, intravascular, cardiovascular	II	X		X	
DTL	Adapter, stopcock, manifold, fitting, cardiopulmonary, bypass	II	X	X	X	
DTM	Filter, blood, cardiopulmonary bypass, arterial line	II	X		X	X
DTN	Reservoir, blood, cardiopulmonary	II	X		X	X
DTP	Defoamer, cardiopulmonary bypass	II	X			X
DTR	Heat exchanger, cardiopulmonary bypass	II	X		X	
DTZ	Oxygenator, cardiopulmonary bypass	II	X		X	X
DQX	Wire, guide, catheter	II	X		X	
DQY	Percutaneous catheter	II	X		X	
DWE	Tubing, pump, cardiopulmonary bypass	II	X		X	X
DWS	Instruments, surgical, cardiovascular	I		X	X	
DXE	Catheter, embolectomy	II		X	X	
DXF	Catheter, septostomy	II		X	X	
DXN	Noninvasive blood pressure measurement system	II	X	X	X	
DXT	Injector and syringe, angiographic	II	X		X	X
DXY	Pulse generator, pacemaker, implantable	III	X		X	

\* Possible

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			Direct	Indirect	Adult	Pediatric
DYB	Introducer, catheter	II		X	X	
EAG	Cephalometer	II	X		X	X
EKD	Instrument, cutting operative	I	X		X	
EOB	Nasopharyngoscope (flexible or rigid)	II		X	X	
EOX	Esophagoscope (flexible or rigid)	II		X	X	
EZW	Stimulator, electrical, implantable, for incontinence	III	X		X	
FCK	Instrument, biopsy, suction	II		X	X	
FFP	Rectal dilator	I	X		X	
FGE	Catheter, biliary, diagnostic	II		X	X	
FMF	Syringe, piston	II		X	X	X*
FMG	IV Administration Set-stopcocks	II	X	X	X	X
FOZ	Catheter, intravascular	II	X	X	X	X*
FPA	Intravascular administration set	II	X	X	X	X
FPK	Tubing, fluid delivery	II	X		X	
FRN	Pump, infusion	II	X	X	X	X
FSM	Tray, surgical instrument	I		X	X	X
FTL	Mesh, surgical, polymeric	II		X	X	
FTY	Tape, Measuring, rulers, and calipers-multiple	I	X		X	X
FQH	Lavage, jet	II	X		X	
FWG	Camera, television, endoscopic with audio	I		X	X	X
FZP	Clip, implantable	II	X		X	
GCJ	Laparoscope, general and plastic surgery	II	X	X	X	X
GCY	Apparatus, suction, single-patient use, portable	I	X		X	
GDO	Applier, surgical, clip	I	X	X	X	
GDW	Staple, implantable	II	X	X	X	X
GEI	Device, electrosurgical, cutting and coagulation and accessories	II	X	X	X	
GET	Motor, surgical instrument, pneumatic powered	I		X	X	
GEX	Laser instrument, surgical, powered	II		X	X	
GEY	Motor, surgical instrument, AC powered-power driver	I		X	X	X
GFD	Dermatome, powered	I		X	X	
HAO	Instrument, surgical, non-powered	I	X		X	X
HBB	Motor, drill, pneumatic	II		X	X	
HBC	Motor, drill, electric	II		X	X	
HBE	Drills, burrs, trephines, and accessories (simple, powered)	II		X	X	

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			Direct	Indirect	Adult	Pediatric
HET	Laparoscope, gynecologic (and accessories)	II	x	x	x	
HOG	Burr, corneal, battery-powered	I		x	x	
HOY	Eye shield	I	x		x	x
HQC	Phacofragmentation system	II	x		x	
HRX	Arthroscope	II	x		x	x
HSZ	Instrument, surgical, orthopedic, pneumatic powered and accessory/attachment	U		x	x	
HTF	Curette	I	x		x	
HWB	Extractor	I	x		x	
HWC	Screw, fixation, bone	II		x	x	x
HWR	Driver, prosthesis	I	x		x	
HWT	Template	I	x		x	
HXD	Clamp	I	x		x	
ITX	Transducer, ultrasonic, diagnostic	II		x	x	
IZQ	Injector, contrast medium, automatic	II	x		x	x
JCY	Catheter, infusion (components)	I		x	x	x*
JDZ	Mixer, cement, for clinical use	I		x	x	
JKA	Blood collection sets	II	x	x	x	x*
KDI	High permeability hemodialysis system	II	x		x	x
KFK	Saw, pneumatically powered	I		x	x	
KFM	Pump, blood, cardiopulmonary bypass, non-roller type	III	x		x	
KNT	Gastrointestinal tubes and accessories	II		x	x	x
KNW	Instrument, biopsy	II	x	x	x	
KOD	Catheter, urological	II	x	x	x	
KOG	Endoscope, and/or accessories	II	x	x	x	
KRA	Continuous flush catheter system measurement, blood pressure, noninvasive	II	x	x	x	
KRB	Probe, thermo dilution	II	x		x	
KRH	Ring, annuloplasty	II		x	x	
KZH	Introducer, syringe needle	II		x	x	x
LDF	Electrode, pacemaker, temporary	II	x		x	
LFL	Instrument, ultrasonic, surgical	II	x	x	x	
LGW	Stimulator, spinal-cord, totally implanted for pain relief	III	x		x	
LGZ	Warmer, thermal infusion fluid	U		x	x	x
LHI	IV Administration Set-transfer set	II		x	x	x
LIT	Catheter, angioplasty, peripheral, transluminal	II	x		x	

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LJS	Percutaneous implanted long-term catheter	II	x	x	x	x*
LKK	Pump, infusion, implanted, programmable	III	x		x	x
LNM	Agent, bulking, injectable for gastro-urology use	III	x		x	
LNQ	Intestinal stimulator	III	x		x	
LOE	Stimulator, invasive bone growth	III	x		x	x
LOX	Catheters, transluminal coronary angioplasty, percutaneous	III	x	x	x	
LWP	Pulse generator, dual chamber, implantable	III	x		x	
LWS	Defibrillator, automatic implantable cardioverter	III	x		x	
LTI	Implant, intragastric for morbid obesity	III	x		x	
LXH	Instrument, orthopedic manual surgical	I	x	x	x	x
LXT	Appliance, fixation, nail/blade/plate combination, multiple component, metal composite	II	x		x	
LZG	Pump, infusion, insulin	II		x	x	x
LZP	Aid, surgical, viscoelastic	III		x	x	
LZS	Excimer laser system	III		x	x	
MAF	Stent, coronary	III		x	x	
MAV	Syringe, balloon inflation	II		x	x	
MDM	Instrument, manual, surgical, general use	I	x	x	x	
MDS	Sensor, glucose, invasive	III		x	x	x
MHY	Stimulator, electrical, implanted, for Parkinson's tremor	III	x		x	x
MIA	Needle, spinal, short term	II	x	x	x	
MIH	System, endovascular graft, aortic aneurysm treatment	III		x	x	
MIR	Shunt, portosystemic, endoprosthesis	III		x	x	
MKQ	Processor, cervical cytology slide, automated	III		x	x	x
MLV	Transcatheter septal occluder	III		x	x	x*
NEU	Marker, radiological, implantable	II	x		x	
NFA	Device, coronary saphenous vein bypass graft, temporary, for embolization protection	III		x	x	
NIK	Defibrillator, automatic implantable cardioverter, with cardiac resynchronization	III	x		x	
NIM	Stent, carotid	III		x	x	
NIP	Stent, superficial femoral artery	III		x	x	

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NIQ	Coronary, drug-eluting stent	III		x	x	
NJE	Intracranial neurovascular stent	III		x	x	
NTE	Catheter, carotid, temporary, for embolization capture	II	x	x	x	
NVZ	Pulse generator, permanent, implantable	III	x		x	
OAE	Cardiac ablation catheter, atrial fibrillation	III	x		x	
OCL	Surgical device, for ablation of cardiac tissue	II	x		x	
OCW	Endoscope and/or accessories, inscope	II	x	x	x	

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