Supplementary Online Content

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eTable. Characteristics of Medical Device Safety Communications

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eTable. Characteristics of Medical Device Safety Communications

MDSC publication date	Medical device	Initial approval year [a]	Device Class [a]	Approval pathway [a]	Safety issue	Signal source	FDA action	Highest recall class
26-Jan-2011	Breast implants	1979	3	PMA	Anaplastic large cell lymphoma	Regulator-initiated assessment	Call for caution with approved usage	NA
5-May-2011	Weck Hem-o-Lok Ligating Clips	1990	2	510(k)	Patient death	MDR	Warning of unauthorized indication	II
2-Jun-2011	Thermography	NA	NA	NA	Promotion of and unauthorized and unstudied device	Regulator-initiated assessment	Warning of unauthorized device	NA
25-Aug-2011	ShoulderFlex Massager	NA	NA	NA	Death, near-strangulation	Regulator-initiated assessment	Withdrawal	NA
13-Oct-2011	Surgical fires	NA	NA	NA	Surgical fires	Regulator-initiated assessment	Call for caution with approved usage	NA
10-Feb-2012	Hand-held Dental X-Ray Units	NA	NA	NA	Devices sold online outside the U.S. and directly shipped to customers in the U.S.	Regulator-initiated assessment	Warning of unauthorized device	NA
16-Feb-2012	Spinbrush line of Powered Toothbrushes	NA	NA	NA	Cuts to the mouth and gums, chipped or broken teeth, swallowing and choking on the broken pieces, injuries to the face and eyes	MDR	Call for caution with approved usage	NA
10-May-2012	Chronic Cerebrospinal Venous Insufficiency Treatment	NA	NA	NA	Death from bleeding in the brain, permanent paralysis from a stroke	Regulator-initiated assessment	Warning of unauthorized device	NA
25-May-2012	Dialysate	1981	2	510(k)	Alkali dosing errors that occurred during hemodialysis using dialysate concentrates containing acetic acid and acetate	MDR	Call for caution with approved usage	NA
30-May-2012	Blunt-Tip Suture Needles	NA	NA	NA	Using blunt-tip suture needles reduces the risk of needlestick injuries	Scientific publications	Use device instead of less safe option	NA
8-Jun-2012	Other-Sonic Generic Ultrasound Transmission Gel	1996	2	510(k)	Colonization or infection with the bacteria Pseudomonas aeruginosa	MDR	Withdrawal	I
28-Jun-2012	ev3 Onyx Liquid Embolic System	2005	3	PMA	Patient deaths and catheter breakage that may be related to catheter entrapment	MDR	Call for caution with approved usage	NA
8-Aug-2012	Stryker Wingspan Stent System	2005	2	HDE	Change in indications due to results from publications	Scientific publications	Call for caution with approved usage	NA
16-Aug-2012	St. Jude Riata Implantable Cardioverter Defibrillator Leads	2002	3	PMA	Premature erosion of the insulation around the electrical conductor wires potentially resulting in death	MDR	Call for caution with approved usage	I

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28-Sep-2012	Mammography Medisound, Inc./Digital Radiology Center, in Kissimmee	NA	2	NA	Poor quality images and possible unreliable results	Regulator-initiated assessment	Warning of specific lots/providers	NA
17-Jan-2013	Metal-on-Metal Hip Implants	2000	2	510(k)	Metal release which may cause damage to bone and/or soft tissue surrounding the implant and joint	Regulator-initiated assessment	Call for caution with approved usage	II
27-Mar-2013	Stryker Neptune Waste Management Systems	1999	2	510(k)	Death and injury	MDR	Withdrawal	I
19-Apr-2013	Covers for Medical Bed Mattresses	NA	NA	NA	Mattress covers failing to prevent blood and body fluids from leaking into the mattress	MDR	Call for caution with approved usage	NA
7-May-2013	Covidien Endo GIA Articulating 60-3.5 Surgical Stapler Reloads	2010	2	510(k)	Stapler Reloads labeled sterile were stolen from the manufacturer prior to sterilization	MDR	Warning of specific lots/providers	NA
13-Jun-2013	Cybersecurity for Medical Devices and Hospital Networks	NA	NA	NA	No any patient injuries or deaths	Homeland security	Call for caution with approved usage	NA
27-Jun-2013	Mammography Problems at San Sebastian X-Ray in San Sebastian, Puerto Rico	NA	2	NA	Poor quality mammograms.	Regulator-initiated assessment	Warning of specific lots/providers	NA
17-Oct-2013	St. Jude Amplatzer Atrial Septal Occluder	2001	3	PMA	Erosions associated with the device	MDR	Call for caution with approved usage	NA
3-Dec-2013	Phillips Automated External Defibrillators	2004	3	510(k)	Internal AED electrical component failure	MDR	Call for caution with approved usage	I
12-Dec-2013	Nipple Aspirate Test	2003	2	510(k)	Promotion of unproven and unauthorized medical device	Regulator-initiated assessment	Withdrawal	I
17-Apr-2014	Laparoscopic Uterine Power Morcellation	1997	2	510(k)	Risk of tumor spread	Regulator-initiated assessment	Warning of unauthorized indication	NA
29-Apr-2014	GenStrip Blood Glucose Test	2012	2	510(k)	Extensive violations of federal quality manufacturing regulations	Regulator-initiated assessment	Withdrawal	NA
23-May-2014	Sterrad Cyclesure 24 Biological Indicator	2011	2	510(k)	Critical shortage of device	MDR	Other	NA
23-Jun-2014	Mammography at Big Sky Diagnostic Imaging, LLC in Butte, Montana	NA	2	NA	Deficiencies in clinical cases submitted for facility's accreditation renewal application	Regulator-initiated assessment	Warning of specific lots/providers	NA

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5-Aug-2014	Enhancement Medical's "Expression" Intranasal Splint	NA	NA	NA	Swelling, tenderness, firmness, bumps, bruising, pain, redness, discoloration, itching, and the development of hard nodules	MDR	Warning of unauthorized indication	I
21-Jan-2015	Bone Graft Substitutes Containing Recombinant Proteins or Synthetic Peptides	2001	3	PMA	Usage in patients under age 18 leading to injuries, such as excess bone growth, fluid accumulation, inhibited bone healing, and swelling	Scientific publications	Warning of unauthorized indication	NA
19-Feb-2015	Endoscopic Retrograde Cholangiopancreatography (ERCP) Duodenoscopes	NA	2	NA	Transmission of infectious agents including Carbapenem-Resistant Enterobacteriaceae	MDR	Call for caution with approved usage	NA
24-Mar-2015	Mammograms at Richard D. Adelman M.D. in Raleigh, North Carolina	NA	2	NA	Deficiencies in clinical cases submitted for facility's accreditation renewal application	Regulator-initiated assessment	Warning of specific lots/providers	NA
13-Apr-2015	Mammograms at J. Bruce Jacobs M.D., Inc.	NA	2	NA	Deficiencies in clinical cases submitted for facility's accreditation renewal application	Regulator-initiated assessment	Warning of specific lots/providers	NA
30-Apr-2015	Mammograms at Coastal Diagnostic Center in Pismo Beach	NA	2	NA	Deficiencies in clinical cases submitted for facility's accreditation renewal application	Regulator-initiated assessment	Warning of specific lots/providers	NA
28-May-2015	Soft Tissue Filler	1981	3	PMA	Block of blood vessels and blood supply restriction to tissues	Scientific publications	Call for caution with approved usage	NA
31-May-2015	Hospira LifeCare PCA3 and PCA5 Infusion Pump Systems	2004	2	510(k)	No patient adverse events or unauthorized device access related to these vulnerabilities	Regulator-initiated assessment	Call for caution with approved usage	NA
13-Jul-2015	LARIAT Suture Delivery Device	2006	2	510(k)	Death, cardiac laceration and/or perforation, hemorrhage, hypotension, pericardial and pleural effusion, cardiac tamponade	MDR	Warning of unauthorized indication	NA
31-Jul-2015	Hospira Symbiq Infusion System	2012	2	510(k)	No patient adverse events or unauthorized access of device	Homeland security	Withdrawal	NA
5-Aug-2015	LVAD	2008	3	PMA	Increase in the rate of pump thrombosis events, strokes	Scientific publications	Call for caution with approved usage	NA
17-Aug-2015	Mammograms at Boston Diagnostic Imaging in Orlando, Florida	NA	2	NA	Problems associated with the quality of mammograms	Regulator-initiated assessment	Warning of specific lots/providers	NA
17-Sep-2015	Flexible Bronchoscopes	1981	2	510(k)	Infections or device contamination associated with flexible bronchoscopes	Regulator-initiated assessment	Call for caution with approved usage	II

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28-Sep-2015	Cranial Perforators with an Automatic Clutch Mechanism	NA	2	NA	Injuries due to mechanism failing to disengage	MDR	Call for caution with approved usage	NA
5-Oct-2015	Bioprosthetic Aortic Valve	1967	3	PMA	Reduced leaflet motion, including both SAVR and TAVR devices	Scientific publications	Call for caution with approved usage	NA
15-Oct-2015	Heater-Cooler Devices	1989	2	510(k)	Nontuberculous Mycobacteria infections	MDR	Call for caution with approved usage	II
13-Nov-2015	Ultrasonics Endoscope Washer/Disinfectors	1984	2	510(k)	Inability to validate adequate washing and disinfection of endoscopes	Regulator-initiated assessment	Withdrawal	II
21-Nov-2015	Intravascular Medical Devices	1985	2	PMA	Pulmonary embolism and infarction, myocardial embolism and infarction, embolic stroke, tissue necrosis, death	MDR	Call for caution with approved usage	I
22-Dec-2015	Hand-held Laser Pointers	NA	NA	NA	Pilots experiencing temporary “flash-blinding”	Regulator-initiated assessment	Other	NA
23-Dec-2015	FUJIFILM Medical Systems Model ED-530XT Duodenoscopes	2015	2	510(k)	Initiation of testing to validate the revised reprocessing instructions	MDR	Call for caution with approved usage	II
5-Jan-2016	Customed, Inc. Surgical Convenience Packs and Trays	1990	2	510(k)	Voluntary recall of all its surgical convenience packs due to potentially compromised sterility	MDR	Withdrawal	I
19-Feb-2016	Pentax Medical Duodenoscope Model ED-3490TK	2009	2	510(k)	Potential disease transfer	MDR	Call for caution with approved usage	II
25-Feb-2016	Neurosurgical Head Holders (Skull Clamps)	1980	2	510(k)	Slippage resulting in patient injuries	MDR	Call for caution with approved usage	NA
15-Mar-2016	Olympus Duodenoscope - TJF-160F and TJF-160VF	2002	2	510(k)	Submitted test protocols and data to validate reprocessing instructions	MDR	Call for caution with approved usage	II
29-Mar-2016	OxySure Portable Emergency Oxygen System, Model 615	2005	2	510(k)	Insufficient oxygen flow, re-breathing of exhaled gases, burns, contusions, chemical exposure	MDR	Withdrawal	II
1-Jun-2016	LivaNova PLC Stöckert 3T Heater-Cooler Systems	2006	2	510(k)	Infection with M. chimaera	Scientific publications	Call for caution with approved usage	II
25-Aug-2016	Programmable syringe pumps	NA	NA	NA	Over- and under- infusion of high risk or life-sustaining medications, occlusion, detection failures, inadvertent boluses, therapy delays	MDR	Call for caution with approved usage	NA
1-Sep-2016	Sciex Mass Spectrometers	2010	1	NA	Potential inaccurate clinical diagnosis	MDR	Call for caution with approved usage	II

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7-Sep-2016	Screening tests for ovarian cancer	NA	NA	NA	Marketing of test with unsupported claims	Regulator-initiated assessment	Warning of unauthorized device	NA
11-Oct-2016	St. Jude Medical ICD and CRT-D Devices	2007	3	PMA	Battery drainage within a day to a few weeks after an ERI alert	MDR	Call for caution with approved usage	I
22-Dec-2016	ZIKV Detect IgM Capture ELISA (InBIOS)	2016	NA	EUA	Higher than expected false positive results	MDR	Call for caution with approved usage	NA
9-Jan-2017	St. Jude Medical's Implantable Cardiac Devices and Merlin@home Transmitter	2014	3	PMA	No reports of patient harm related to these cybersecurity vulnerabilities.	Homeland security	Call for caution with approved usage	II
11-Jan-2017	Implantable Infusion Pumps	1989	3	PMA	Patient injury and death	MDR	Call for caution with approved usage	NA
13-Jan-2017	FUJIFILM older duodenoscope models	2015	2	510(k)	Potential disease transfer	MDR	Withdrawal	II
9-Mar-2017	SPS-1 Static Preservation Solution Distributed by Organ Recovery Systems	2010	2	510(k)	No reports of any post-operative infections or other adverse events directly linked to the identified products	MDR	Warning of specific lots/providers	II
17-May-2017	Magellan LeadCare, LeadCare II, LeadCare Plus, and LeadCare Ultra	1997	2	510(k)	Inaccurate results when processing venous blood samples resulting in lead poisoning	MDR	Call for caution with approved usage	I
15-Jun-2017	Frameless Stereotaxic (Stereotactic) Navigation Systems	1999	2	510(k)	Navigational accuracy errors during surgical procedures	MDR	Call for caution with approved usage	NA
29-Aug-2017	Abbott's (formerly St. Jude Medical) pacemaker and CRT-P devices	1989	3	PMA	Unknown cyber vulnerability - no impact yet	MDR	Call for caution with approved usage	II
7-Nov-2017	Laserworld and Ray Technologies International Laser Projectors	NA	NA	NA	Lack of required safety features. Devices did not function in a safe manner	Regulator-initiated assessment	Other	NA
14-Nov-2017	Injectable Silicone for Body Contouring and Enhancement	NA	NA	NA	Marketing of unauthorized device / unauthorized indication in unauthorized settings	Regulator-initiated assessment	Warning of unauthorized indication	NA

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3-Jan-2018	Mammograms at Palm Beach Broward Medical Imaging Center in Deerfield Beach, Florida	NA	2	NA	Mammography machine failed quality test. Unknown impact	Regulator-initiated assessment	Warning of specific lots/providers	NA
17-Jan-2018	Zoll LifeVest 4000 Wearable Cardioverter Defibrillator	2009	3	PMA	Device failure	MDR	Call for caution with approved usage	II
17-Apr-2018	Certain Abbott (formerly St. Jude Medical) Implantable Cardiac Devices	2007	3	PMA	Rapid Battery Depletion and cybersecurity error of unknown importance	MDR	Call for caution with approved usage	I
29-May-2018	Surgical fires	NA	NA	NA	Injury and death	MDR	Call for caution with approved usage	NA
30-Jul-2018	Energy-Based Devices to Perform Vaginal 'Rejuvenation' or Vaginal Cosmetic Procedures	NA	NA	NA	Marketing of unauthorized device / unauthorized indication	Regulator-initiated assessment	Warning of unauthorized device	NA
14-Sep-2018	Alcon CyPass Micro-Stent	2016	3	PMA	Damage to the cells lining the cornea	Regulator-initiated assessment (PAS)	Withdrawal	I
27-Sep-2018	Pen needles	NA	NA	NA	Hyperglycemia, death	MDR	Call for caution with approved usage	NA
28-Sep-2018	Mammography Problems at Aims Diagnostic Imaging in Manahawkin, NJ	NA	2	NA	Mammography machine failed quality test. Unknown impact	Regulator-initiated assessment	Warning of specific lots/providers	NA
22-Oct-2018	Raindrop Near Vision Inlay	2016	3	PMA	Risk of developing of corneal haze	Regulator-initiated assessment (PAS)	Withdrawal	I
31-Oct-2018	Genetic Tests with Unapproved Claims	NA	NA	NA	Marketing / usage of unauthorized device / unauthorized indication	Scientific publications	Warning of unauthorized indication	NA
14-Nov-2018	Implanted Pumps for Intrathecal Administration of Medicines for Pain Management	1982	3	PMA	Marketing / usage of unauthorized device / unauthorized indication	MDR	Warning of unauthorized indication	NA
20-Dec-2018	Teething Necklaces, Bracelets, and Other Jewelry	NA	NA	NA	Death and choking in children	MDR	Warning of unauthorized device	NA

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31-Jan-2019	Air-in-Line alert for Infusion Pumps, Fluid Warmers, and Rapid Infusers	NA	NA	NA	False "air-in-line" alarms causing delays in therapy	MDR	Call for caution with approved usage	NA
28-Feb-2019	Robotically-Assisted Surgical Devices in Women's Health	NA	2	510(k)	Marketing / usage of unauthorized device / unauthorized indication	Regulator-initiated assessment	Warning of unauthorized indication	NA
21-Mar-2019	Medtronic Implantable Cardiac Devices, Programmers, and Home Monitors	2002	3	PMA	Unknown cyber vulnerability - no impact yet	MDR	Call for caution with approved usage	II
8-Apr-2019	Previously Owned Test Strips or Test Strips Not Authorized for Sale in the United States	NA	NA	NA	Marketing / usage of unauthorized device / unauthorized indication	Scientific publications	Warning of unauthorized device	NA
12-Apr-2019	Use Cleared or Approved Medical Devices to Help Assess or Diagnose a Head Injury and Concussion	NA	NA	NA	Marketing / usage of unauthorized device / unauthorized indication	Scientific publications	Warning of unauthorized device	NA
25-Apr-2019	Wingspan Stent System	2005	2	HDE	Higher incidence of stroke or death	Regulator-initiated assessment	Warning of unauthorized indication	NA
26-Apr-2019	Mammography Problems at East Palestine	NA	2	NA	Mammography machine failed quality test. Unknown impact	Regulator-initiated assessment	Warning of specific lots/providers	NA
7-May-2019	Medtronic Pacemakers	2017	3	PMA	Early battery drainage	MDR	Call for caution with approved usage	NA
17-May-2019	Devices for Diabetes Management Not Authorized for Sale in the United States	NA	NA	NA	Insulin overdose requiring medical intervention	Scientific publications	Warning of unauthorized device	NA
27-Jun-2019	Certain Medtronic MiniMed Insulin Pumps	2000	2	510(k)	Unknown cyber vulnerability - no impact yet	Homeland security	Call for caution with approved usage	I
1-Oct-2019	Devices with Interpeak IPnet TCP/IP stack (VxWorks)	NA	NA	NA	Unknown cyber vulnerability - no impact yet	Homeland security	Call for caution with approved usage	NA
28-Oct-2019	Endologix AFX Endovascular AAA Graft Systems	2011	3	PMA	Endoleak - device failure	Scientific publications	Call for caution with approved usage	I

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5-Nov-2019	Troponin lab test - biotin technology	1996	2	510(k)	Possible error in troponin level	MDR	Call for caution with approved usage	NA

EUA = Emergency Use Authorization; HDE = Humanitarian Device Exemption; MDR = Medical Device Reporting; MDSC = Medical Device Safety Communication; NA = Not Available; PAS = Post-Approval Studies; PMA = Premarket approval

[a] For some MDSCs, data regarding approval year, device class and / or approval pathway were not available. These include MDSCs for devices never authorized by the Food and Drug Administration, MDSCs whose subject was not a specific device and MDSCs referring to providers rather than specific devices.

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