Newly Approved Devices

Recently Approved Devices

(searchable listing):

https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/Recently-ApprovedDevices/ucm596872.htm

Premarket Approval Final Decisions:
https://www.fda.gov/downloads/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/UCM599568.pdf

510(k)s Final Decisions:
https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm603348.htm

In Brief

As of April 2, 2018

For the FDA Enforcement Report containing the most recent Class I, II and III recalls, go to
http://www.accessdata.fda.gov/scripts/ires/index.cfm

If you see any problems of the type described in these announcements or other device safety issues, please report them through the MedSun reporting system at https://medsun.fda.gov as soon as possible. If you need password information or want to report by phone, please call us at 1-800-859-9821 or e-mail at medsun@fda.hhs.gov.

Recalls and Safety Alerts

BD Vacutainer Blood Collection Tubes by Becton, Dickinson and Company (BD): Class I Recall
March 23, 2018

BD is recalling their Vacutainer EDTA Blood Collection Tubes with lavender, tan, pink and green rubber tube stoppers due to a chemical in the rubber tube stopper that interferes with the accuracy of the Anodic Stripping Voltammetry (ASV) testing methodology. This chemical reaction makes it difficult for the Magellan lead tests to detect the correct amount of lead in the sample and may cause falsely lower test results. Falsely lower test results may lead to improper patient management and treatment for lead exposure or poisoning.

Cardiac Resynchronization Therapy with Defibrillation (CRT-Ds) and Implantable Cardiovert-Defibrillators (ICDs) by Medtronic: Class I Recall
February 27, 2018
Medtronic is recalling certain ICDs and CRT-Ds due to a defect in the manufacturing process. This defect causes an out of specification gas mixture inside the device and may prevent the device from delivering the electrical shock needed to pace a patient's heartbeat or revive a patient in cardiac arrest. The delay or inability to deliver a shock to a patient in cardiac arrest or pace a patient's heart whose heartbeat is too slow could result in serious injury and/or death.

HeartStart MRx Defibrillator by Philips Electronics: Class I Recall
February 9, 2018
As a result of this GDT defect, the HeartStart MRx may fail at any time, including when delivering repeated shocks in AED mode, or during the periodic Operational Check outlined in the device's Instructions for Use. If the device is used in AED mode after failure, the device will not deliver patient therapy. Continued use of the device in AED mode after failure may lead to serious patient injury or death.

HIGHLIGHTED REPORTS

The reports that follow represent a cross section of device-related events submitted by MedSun Reporters during March 2018 The reports are displayed within clinical specialty areas based on analysis of the information submitted. The reports are presented as submitted by MedSun Representatives and in some instances have been summarized and/or edited for clarity.

A database of all MedSun reports can be found at:

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/medsun/SearchReportText.cfm

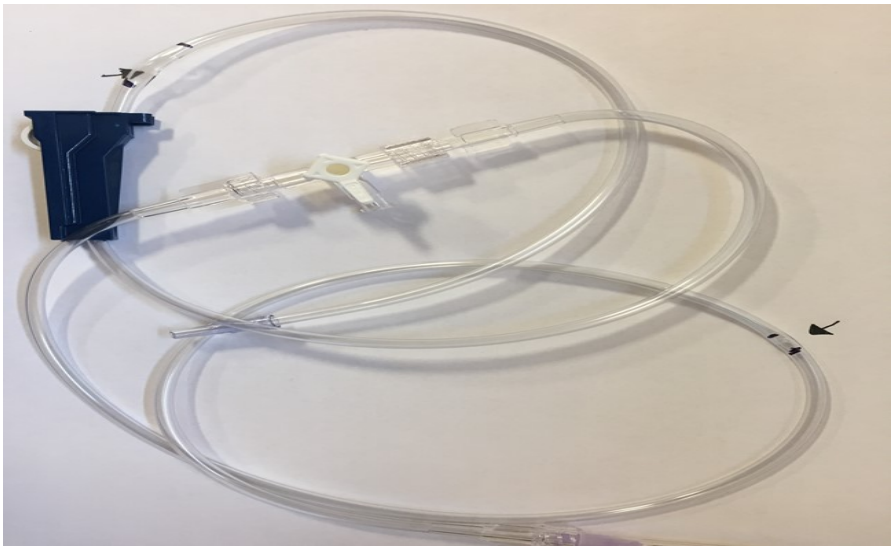

Special Note:

The lollipop icon distinguishes highlighted reports that describe medical device events involving neonatal or pediatric patients, or those events involving a medical device that is indicated for use in neonatal and pediatric patient populations. FDA defines pediatric patients as those who are 21 years of age or younger (that is, from birth through the twenty-first year of life, up to but not including the twenty-second birthday) at the time of the diagnosis or treatment.

Device	Manufacturer	Problem
Agent, Absorbable Hemostatic	Baxter Healthcare	Risk management recently received eight incidents reporting that Neurosurgery clinic patients had adverse skin reactions to the Baxter Floseal liquiband skin glue that was used during recent surgical cases. All eight patients have presented to the Neurosurgery clinic complaining of skin issues at or near their surgical sites where the glue was applied. All patients have required some intervention in response to the reactions.

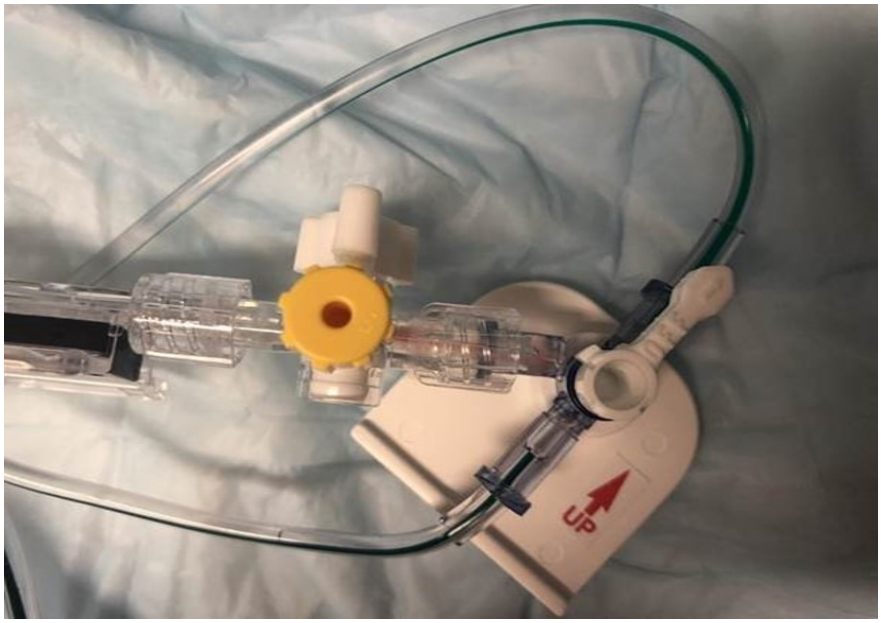
Device	Manufacturer	Problem
Aortic Punch Lot #: 74H1702723 Cat #: MDP-60K Other #: *+H196MDP60K1W*	Teleflex Medical	When doctor used the 6.0 mm punch on the external iliac artery he said it "disintegrated" and stuck to the tissue. He had difficulty removing it. The punch caused damage to the tissue and the external iliac artery. It necessitated us "going back into slush". The damage to the tissue required us to call the vascular team to come in and repair the artery with a graft. The device and packaging were saved and brought to Clinical Engineering for evaluation. An exemplar from the same lot was also obtained. It seems a piece of tissue was jammed between the cutting ring and the center plunger and the plastic ring on the end of the instrument broke off when the action was reversed, making it impossible to clear the jammed tissue. Exemplar device from same lot was tested with a piece of rubber glove. While it punched a hole in the glove, the punched-out section jammed in the cutter. When trying to free the jam, the plastic ring popped off and flew across the room and was lost. So there are two issues; the cutter tends to jam and the plastic ring on the distal end of the device is easy to break off when trying to clear a jam. Please see pictures below:  

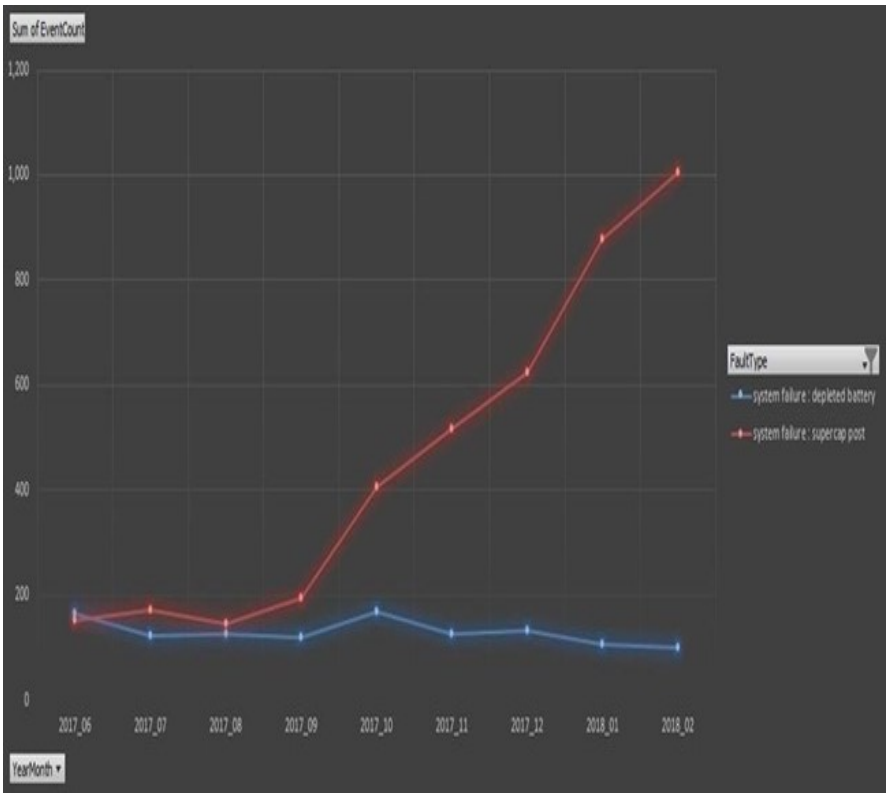
Device	Manufacturer	Problem
Bed, Ac-powered Adjustable Brand: Sizewise Bari Rehab Platform 2 Model#: BB280 Other #: Barcode:070632592	SUNFLOWER MEDICAL L.L.C.	Patient was on Sizewise bed receiving care with bed in an elevated position. After care was rendered, CNA was lowering bed to lowest position (for patient safety). CNA heard a pop and saw a flash. Looked under bed and noticed that the cord from the bed's blower was caught between the wheel cover and the bedframe, this cut the outer coating of the cord as well as one of the wires within the cord. Black (scorch) mark noted on wheel cover. Cord unplugged from blower. Vendor (Sizewise) called for replacement cord. There is a concern for the lack of a track or other employed means on the bed to keep the cord away from the bed's moving parts/pinch points.
Device 1: Bed, Air Fluidized Brand: Envella Bed Model#: P0819A **Device 2: Pump, Infusion** Brand: Sigma Spectrum Infusion Pump Model#: 35700BAX Cat #: 35700BAX	HILL-ROM, INC. Baxter Healthcare Corporation	Nursing reported Baxter Sigma infusion pump repeatedly alarming EC 341 while connected and infusing to a patient who was in a Hill-Rom Envella bed. Nursing's response was to switch out the pumps when this occurred, but the problem persisted. The pumps were connected to the AC outlet in the patient's room. Additionally, the patient reported being shocked when touching a metal object (nursing call bell, chain on the Hill-Rom trapeze hanging over his bed). Medical Engineering downloaded the pump's history and saw the EC 341 error repeatedly. The Engineer ran three pumps together in the patient's room using a demo set in each pump. The pumps ran for an hour without alarming. Nursing then connected one of the pumps to the patient in the Envella bed, and within ten minutes, the pump started to alarm and displayed the EC 341 error. An electrical safety check was performed on the bed, and the bed passed.
Cable, Transducer And Electrode, Patient, (Including Connector) Brand: Vital Signs Lot #: 0001189010 Other #: A46X29XX	Carefusion	When preparing and setting up anesthesia breathing circuit for next case, it was noted that the CO2 nipple attachment on the elbow of the adult breathing circuit did not have a hole in it for flow and monitoring. It is closed, no opening. Therefore, device would not function properly for anesthesia if needed to use. All of the said lot number have been pulled from stock.

Device	Manufacturer	Problem
Device 1: Catheter, Intravascular, Therapeutic, Long-term Greater Than 30 Days Brand: Sherlock 3cg Tip Location Lot #: RE-BY0838 **Device 2: Central Venous Catheter Navigation System, Electrocardiographic/ magnetic** Brand: Sherlock Site-rite System Model#: Sherlockv1.1.2 Cat #: Sherlock-v1.1.2	Bard Access Systems, Inc. Bard Access Systems, Inc.	PICC line placed with Sherlock 3cg technology. Sherlock confirmed placement of PICC in SVC (Superior Vena Cava). Patient developed arrhythmias after PICC line placed. MD ordered multiple tests to find source of arrhythmia over 2-3 days. CT result showed catheter in right atrium. PICC line was pulled back 3cm and placement verified by xray. Patient was not on telemetry before PICC was placed. Patient was noted to be in normal sinus rhythm per ECG BARD device. Patient was noted to be in normal sinus rhythm while under the care of the Vascular Access RN. Additional tests required due to arrhythmia after Sherlock confirmed PICC placement: Gated CTA, CXR, Echo. The patient was started Cardizem. No heparin (anticoagulant). The PICC Catheter was secured with a stat-lock and dressing (per protocol). Migration did not occur per the knowledge of the Vascular Access RN. Both the Sherlock and ECG confirmation techniques were utilized to confirm PICC placement. PICC remained in place. No other known problem such as this has occurred since the initial implementation of the 3CG/ECG confirmation system. "I had no difficulty with placement at all. The patient did have a spinal cord stimulator in place with electrodes in his upper thoracic spine (the battery of the device was dead, so the device was off). The catheter was advanced until the P-wave spiked and turned green. No negative deflection was ever noted. Normal sinus rhythm continued throughout placement; no arrhythmias or ectopy noted. No complaints or symptoms noted by the patient during or after placement as assessed by myself", Vascular Access RN.
General Surgery Tray Brand: Thoracentesis Tray Lot #: Tray:T1258413 Tubing:H1213855 Other #: Thoracentesis Tray lot T1258413	MERIT MEDICAL SYSTEMS, INC	This is one of several reoccurring kinked tubing incidents. While setting up for a thoracentesis procedure approximately a week ago at 10am, the custom fluid Management tubing demonstrated a kink. A new thoracentesis tray was opened. The tube from the newly opened tray was used as a substitute. Lot number for thoracentesis tray (T1258413). Lot number for custom fluid Management kit (H1213855). This tubing lot number differs from previously submitted reports. Please see picture below: 

Device	Manufacturer	Problem
Dermatome Brand: Zimmer Air Dermatome Handpiece Cat #: 00-8801-001-00	Zimmer, Inc.	Reportedly, while attempting to obtain a skin graft off of a patient's lower extremity, the blades were able to be applied to the Dermatome incorrectly (backwards) causing injury to the patient's skin graft site. Submitting this report for possible design flaw.
Lift, Patient, Non-ac-powered Brand: Cirrus Model#: 600	Tollos, Inc.	While transferring a patient from the bed to a stretcher, the lift snapped, came off the track in the ceiling and fell onto the patient. A transporter was with the patient and attempted to stop it from hitting the patient. The transporter suffered a broken arm as a result. Afterwards the patient complained of hip pain. X-rays were done to confirm no further injury. Biomed confirmed that the safety pin on the track was missing.
Set, Administration, Intravascular Brand: Zyno Model#: B2-70072-F Cat #: B2-70072-F	Zyno Medical, LLC.	Etoposide (VP16) was running on a pump for a patient. The pump was alarming, so the RN checked on the pump. Pump read occlusion, so the tubing was changed, and the drug started running again for some time. The pump alarmed for occlusion again, so the RN checked the filter on the tubing. The filter exploded, spilling etoposide on the chemo gown, goggles, IV pole, and floor. A chemo spill kit was used to clean the area. No harm came to the patient and treatment was eventually completed. The faulty administration sets were not saved due to the chemotherapy contamination.
Set, Administration, Intravascular Brand: Alaris, Smartsite Model#: 10404198 Cat #: 10404198	CAREFUSION 303, INC.	Collectively over the past week or so we've had 10 infusion sets at issue (see descriptions below). There was no patient harm so there is no patient information in this report. All but item 1 were issues with non-priming capabilities; 3 of which were from Emergency room and six were from Pediatrics/L&D. Since the Reference numbers and ID numbers were identical on the saved devices the consensus was to get the FDA notified of the trend. 1. Pump tubing broke while in Emergency patient was in CT. The blue piece snapped right at the end of the infusion. The tubing was not being pulled on in any way; we were in the control room and the pump said infusion complete and then seconds later the tubing snapped loose from the top of pump and shot up in air and dumped the last little bit of ABX onto the bed. 2, 3, & 4. Many pump tubings in the Emergency Room have problems with initial priming of line. Free flow does not occur until some pressure is applied to cause the backflow valve to "pop" open internally. 5 & 6 from L&D and 7-10 Pediatrics with the similar issue: IV tubing would not prime and pump was unable to infuse IV fluids. Pump tubing changed 3 times and pump channel changed twice.

Device	Manufacturer	Problem
Pump, Infusion Brand: Plum 360 Model#: 30010 Cat #: 30010	Hospira, Inc.	ICU Medical (Hospira's) Plum 360 units are deteriorating to the point of causing breakage on the stress joint points between the front and back casings. Hospira has been notified and we are replacing the broken cases. After investigation, it was determined by ICU Medical that our current cleaning agent is the one causing the deterioration of the plastic. We use CaviCide and it is currently been replaced by an approved ICU Medical cleaning agent. We wanted to report this as the damage on the casings utilizing CaviCide is extensive. By our experience, actual damage will start physically showing after @ 12 to 18 months after continuous cleaning and disinfection. A broken casing creates sharp edges that could cause an injury to the patient or device operator. Please see pictures below:  

Device	Manufacturer	Problem
Shunt, Central Nervous System and Components Brand: Limitorr Volume Limiting External Csf Drainage And Monitoring System Model#: INS9020SP1 Lot #: 1172935 Cat #: INS9020SP1	Integra Lifesciences Corporation	LimiTorr EVD/LSAD drain setup found to be broken at connection site, no obvious cause noted at the time. NS resident doctor notified to change EVD setup. Survey of staff found this had happened a few times before. Pictures were taken of broken device and lot number was noted. Please see picture below: 
Stopcock, I. V. Set Brand: Smallbore Trifuse Ext Set W/3 Microclave® Lot #: 3537506 Cat #: B3383	ICU Medical, Inc.	ICU Medical Tri fuse extension device REF B3383 Lot number 3537506. Extension set is breaking or "snapping" at the point of trifurcation. Leading to accidental chemotherapy exposure, risk of infection and patient safety issue. This has happened several times over the past few weeks. Risk extends to several patients. Per site reporter: Manufacturer response for Trifuse ext set, They have replaced this lot from our stock.

Device	Manufacturer	Problem
Syringe Infusion Pump Brand: Medfusion 4000 Model#: 4000	Smiths Medical, Inc.	A large number of Medfusion pumps in our fleet have been showing the fault 'System Failure: Supercap Post'. The hospital has tried a few different ways of supporting the assets including battery and board replacements. Smith's medical has been notified but no progress has been made. The issue has been escalating since October of last year and the reports out of the Pharmguard server show the the number of unique serial numbers to have a 'System Failure: Supercap Post' fault has increased from 157 in September last year to 271 in February of this year. The number of 'System Failure: Supercap Post' events has increased from 383 to 1,193 in six months. This is out of a fleet of 707 Medfusion 4000 pumps. The surge in failures causes frustration for the staff because of the shortage of pumps. This has resulted in delays to care and submission of incident reports by staff. We have also analyzed the 'system failure: depleted battery' Events for the pumps which has actually declined over the same period suggesting that these supercap failures are a separate issue than the battery being run too long. When cycling the power of the same pump will sometimes come back normally and other times show the fault. The inconsistency makes it difficult to determine the root cause of the problem. See attached image of surge in 'System Failure: Supercap Post' faults. Please see picture below: 

Device	Manufacturer	Problem
System, X-ray, Fluoroscopic, Image-intensified Brand: Insight 2 Model#: Insight 2 Other #: XRY0358	Hologic Inc.	Biomed was called to the repair a c-arm at a remote clinic. We identified that the power supply was faulty. After investigating what on the power supply failed, we opened up the metal case of the power supply. (by force as this is not a case meant to be opened.) We found the battery had caught fire. (picture attached to this report) We called the vendor and asked if this battery was meant to be replaced. They stated it was not part of a pm. It served as a backup in case of power loss, much like a UPS. Our unit was approx. 5 years old. Please see picture below: 
Tank, Oxygen Brand: ECylinder Model#: Oxygen, Compressed USP UN1072 Lot #: W1128023TB10 Other #: REE263, DOT3AA2015, PCGC0577534	Airgas Healthcare	The gauge on the oxygen tank read as full but when the tank was turned on there was no flow. This happened during a code blue event. The initial tank worked, but the back-up tank did not. Due to high flow O2 use the initial tank ran out and had to be replaced by a back-up tank. The regulator on the new tank did not produce any flow from the new "E" cylinder tank that showed full pressure. A Respiratory Therapist was operating the device at the time of the event. Per manufacturer response to the hospital, the device is pending examination by vendor.

Device	Manufacturer	Problem
Device 1: Instrument, Ultrasonic Surgical Brand: Harmonic Ace Model#: HARH36 Cat #: HARH36 **Device 2: Instrument, Ultrasonic Surgical** Brand: Harmonic Ace Model#: HARH36 Cat #: HARH36	ETHICON ENDO-SURGERY, LLC ETHICON ENDO-SURGERY, LLC	During the surgical procedure, the white portion of the device in the "jaw" peeled away from the jaw, occurring less than 5 minutes of use by the surgeon. Three harmonic instruments were opened and used due to the same reoccurring event problem. There was no harm to the patient; all pieces remained attached to the instruments.