



Women Advocating Reproductive Safety



October 6, 2014

Division of Docket Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Rm. 1061  
Rockville, MD 20852

**Comments of Members of the Patient, Consumer, and Public Health Coalition  
on Draft Guidance**

***“Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket  
Notification Requirements”***

**[Docket No. FDA-2014-D-0967]**

As members of the Patient, Consumer, and Public Health Coalition and other advocacy groups, we appreciate the opportunity to comment on the draft guidance, *Intent to Exempt Certain Class II and Class I Reserved Medical Devices from Premarket Notification Requirements*. The draft guidance lists the medical devices that the Food and Drug Administration (FDA) intends to exempt from premarket submission requirements.

The draft guidance states that the devices identified in the guidance “are sufficiently well understood and do not present risks that require premarket notification (510(k)) review to assure

their safety and effectiveness.” **We strongly disagree. Some of the devices do “present risks” and should require the regulatory scrutiny provided by 510(k) premarket notification reviews.**

After checking for adverse event reports in the Manufacturer and User Facility Device Experience (MAUDE) database for the devices listed in the draft guidance, **we found seven devices that had numerous MAUDE injury reports and numerous deaths associated with the devices.** Since MAUDE reports are known to be the tip of the iceberg of adverse reactions, **we question the CDRH decision to no longer require that any scientific information be provided to the FDA regarding the devices listed below, and strongly urge that FDA enforce compliance with 510(k) requirements for them.**

### **Devices with numerous MAUDE reports since 2008**

#### *Cardiovascular Devices*

Trocar devices (product code DRC), which are sharp-pointed instruments used to pierce a vessel or chamber, had 253 MAUDE reports including, 136 reports involving injuries and six reports involving deaths associated with the device. Injuries included a cardiac perforation and a perforation in the aorta.<sup>1,2</sup>

#### *Gastroenterology – Urology Devices*

Esophageal Ligator devices (product code MND) had more than 500 MAUDE reports including, 454 reports involving injuries and 23 reports involving deaths associated with the device. Injuries included severe bleeding.<sup>3</sup> One patient had to go to the emergency room two days after the procedure with the device “because the clip came off inside the patient.”<sup>4</sup>

Mechanical Biliary Lithotripter devices (product code LQC) had more than 500 MAUDE reports including, 161 reports involving injuries and two reports involving deaths associated with the device. Adverse events included perforated duodenum in which an elderly patient died “due to unknown complications after the surgery.”<sup>5</sup> Also, broken lithotripter devices have required doctors to perform “open surgery to retrieve the basket wire” from patients.<sup>6</sup>

Routine Fiberoptic Light Source devices (product code FCW) had more than 500 MAUDE reports including, 19 reports involving injuries associated with the device. Almost all of the injuries involved burns, and one report noted that “the connections between the cord and the retractor gets hot and the surgeons have been dealing with this for years but never said anything.”<sup>7</sup>

Xeon Arc Endoscope Light Source devices (GCT) had 386 MAUDE reports including, 26 reports involving injuries and three reports involving deaths associated with the device. Injuries included third degree burns and other burns.<sup>8</sup> Also, two patients were diagnosed with an air embolism following a procedure with the device, and one “suffered a neurological injury and was not expected to survive.”<sup>9</sup>

Esophageal Dilator devices (product codes EZM, FAT and KNQ) had more than 500 MAUDE reports including, 122 reports involving injuries and two reports involving deaths associated with

the device. Injuries included “a perforation in the patient’s esophagus” which had to be treated with surgery, as well as and numerous reports of balloon ruptures.<sup>10</sup> The patient subsequently developed a subarachnoid hemorrhage and passed away.<sup>11</sup>

### *Anesthesiology Devices*

Portable air compressor devices (product code BTI) have had more than 500 MAUDE reports including, nine reports involving injuries and two reports involving deaths associated with the device. A report that alleges that a nebulizer device caused a fire in a patient’s home;<sup>12</sup> and another report of a fire allegedly caused by the device that resulted in the deaths of three people and serious injuries to a fourth person who required hospitalization.<sup>13</sup>

In light of the large number of MAUDE reports, and serious injuries associated with these devices, we are very concerned that the FDA has proposed to exempt them from premarket notification requirements, thus putting the public at additional risk. Also, we strongly oppose the FDA’s plan to decline to enforce compliance with premarket notification requirements for these devices even before completing the rulemaking procedures necessary to exempt these devices. The draft guidance states, “Until the publication of a final rule or order exempting these devices from 510(k), FDA does not intend to enforce compliance with 510(k) requirements for these devices.” This sends a clear message that the FDA has already made its decision on all of these devices and is not seriously considering public comments, but merely going through the motions of public comments as required by law.

**We strongly urge the FDA to reassess the Submission Type for the above devices and continue to require 510(K) clearance due to the high number of MAUDE reports, including numerous deaths from these devices. Devices that can cause fatal adverse events should not be exempt from FDA regulation.**

Annie Appleseed Project  
Breast Cancer Action  
Connecticut Center for Patient Safety  
Consumers Union  
Jacobs Institute of Women's Health  
National Center for Health Research  
National Committee to Preserve Social Security and Medicare (NCPSSM)  
National Consumers League  
National Physicians Alliance  
National Organization for Women  
Public Citizen  
The TMJ Association  
U.S. PIRG  
WARS  
WomenHeart  
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- <sup>1</sup> MAUDE report for St. Jude Medical, Inc. (Af-Minnetonka) Brk Transseptal Needle (6/9/2014).  
[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_id=4042452](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=4042452)
- <sup>2</sup> MAUDE report for St. Jude Medical, Inc (Af-Minnetonka) Transseptal Needle, Xs, Brk-1, 71cm (6/26/2014).  
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- <sup>3</sup> MAUDE report for Olympus Medical System Corporation Single Use Rotatable Clip Fixing Device (3/17/2014).  
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- <sup>4</sup> MAUDE report for Boston Scientific - Marlborough Resolution Clip Clipping Device Ligator, Esophageal (5/25/2013).  
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- <sup>5</sup> MAUDE report for Boston Scientific - Spencer Trapezoid Rx Lithotripter, Biliary Mechanical (8/4/2014).  
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- <sup>6</sup> MAUDE report for Olympus Medical Systems Corporation Olympus Single Use Mechanical Lithotripter V (7/19/2013).  
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- <sup>7</sup> MAUDE report for Integra Burlington, Ma, Inc. Repair, Light Source LX300 SERI (10/10/2013).  
[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi\\_id=3412994](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfmaude/detail.cfm?mdrfoi_id=3412994)
- <sup>8</sup> MAUDE report For Carefusion Fiber-Optic Light Cable Acmi/Acmi 7.5FT LIGHT SOURCE, ENDOSCOPE, XENON Arc (9/13/2011). [http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_id=2284138](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=2284138)
- <sup>9</sup> MAUDE report for Olympus Medical System Corporation Olympus Evis Exera li Light Source (8/9/2011).  
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- <sup>10</sup> MAUDE report for Boston Scientific - Marlborough Rigiflex li Achalasia Balloon Dilator Dilator, Esophageal (5/9/2014).  
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- <sup>11</sup> MAUDE report for Boston Scientific – Cork Cre Wireguided Balloon Dilator (08/06/2012).  
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- <sup>12</sup> MAUDE report for Respiroics, Inc. Innospire Elegance Nebulizer Compressor, Air, Portable (9/20/2013).  
[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi\\_id=3591183](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfMAUDE/detail.cfm?mdrfoi_id=3591183)
- <sup>13</sup> MAUDE report for Evo Medical Solutions Maxiaspirator (8/24/2010).  
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