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Dockets Management Branch (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Biosense Webster
a Johnson & Johnson company

Re: **Docket No. 02N-0456[1], "Determining Hospital Procedures for Opened-But-Unused, Single-Use Medical Devices"**
and
Docket No. 02N-0534[2], "Medical Device User Fee and Modernization Act of 2002"

Subject: Biosense Webster Position To List "Single Use" Electrophysiology Catheters As Validation For Reuse Required

Biosense Webster, Inc., (BWI) respectfully requests consideration of information presented herein regarding reuse of Electrophysiology (EP) Catheters. BWI believes available evidence demonstrates that diagnostic EP Catheters designated as "single use" devices should be included on FDA's list of devices that will require validation data regarding suitability for reuse prior to clearance for reprocessing.

The Medical Device User Fee and Modernization Act of 2002 (MDUFMA) requires FDA to review by April 26, 2003, the types of single-use devices now subject to 510(k) clearance that may be reprocessed to identify those devices that FDA will require submission of "validation data...regarding cleaning and sterilization, and functional performance" to show that the reprocessed device "will remain substantially equivalent...after the maximum number of times the device is reprocessed as intended" by the person who submits the 510(k). FDA's list of 510(k) devices requiring validation for reuse will be published in the Federal Register.

EP Catheters are precision instruments used to measure fine electrical signals within the human heart. The primary working mechanism consists of various types of electrodes positioned at or near the distal end of the catheters that detect and feedback electrical signals via delicate wires to an external console for processing and displaying the electrical activity of the heart. Electrical signals are also sent from the generator console to the heart for pacing procedures. The continuity of these electrical connections is critical for proper operation of this device. In addition, the tips of these catheters are precisely constructed of a progression of materials composed of different durometers that ensure appropriate maneuverability for proper positioning of the catheter tips within the heart. Some EP Catheters are deflectable and, therefore, include a mechanism (pull wire) inside the catheter that controls deflection.

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[1] "Determining Hospital Procedures for Opened-But-Unused, Single-Use Medical Devices; Request for Comments and Information," Federal Register 67 (No. 167), Page 55269, August 28, 2002.

[2] "Medical Device User Fee and Modernization Act of 2002, Establishment of a Public Docket, 12/31/02, Docket Number 02N-0534" (FDA Website: http://www.fda.gov/cber/mdufma/mudufmadocket.htm).

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These catheters are also manufactured in a range of diameters and lengths. Many therapeutic decisions on how to best treat the patient are based on the information provided by these diagnostic catheters. Although 510(k) cleared EP Catheters are extensively tested to ensure they are robust for one time use as claimed by the manufacturer, there is no assurance that repeated use or repeated cleaning and sterilization will maintain such confidence. Validation data are necessary to provide objective evidence that EP Catheters may be regarded as safe for reuse.

Documentation supporting this position is in "Patients in Danger: The Reuse of Single-Use Medical Devices in Europe" published by EUCOMED[3]. This publication discusses cross-infection, contamination, and impaired performance as major potential categories of harm from reuse of medical devices designed for single-use. EP Catheters are subject to all of these factors if not properly cleaned and resterilized and proven capable of withstanding the stresses of repeated uses. It is not completely known if standard cleaning procedures are capable of removing all contaminants from the electrodes and catheter surfaces. To illustrate this point, this EUCOMED article includes a photograph (provided by BWI) of a red blood cell remaining on a guiding catheter after cleaning and sterilizing for reuse. Impaired performance could be caused by residues remaining after incomplete cleaning of catheters, wear and tear on catheters from repeated use, and/or physical or chemical changes due to repeated exposure to the temperatures and other conditions involved in reprocessing.

Further documentation supporting this position is in "Potential Reuse? A Study of the Private and Professional Reprocessing of Catheters, Guidewires, and Angioscopes" by Andreas Beck[4]. This publication focuses on angiographic and interventional catheters, guidewires, and sheath introducers for endovascular use, but the same principles apply to EP Catheters. Most of the devices studied were examined after they had been used clinically (i.e., exposed to blood and tissues) and then cleaned and resterilized for reuse, but some devices were examined after reprocessing only without clinical use to detect changes due to reprocessing alone. The devices were evaluated mainly using visual observation via light microscopy, electron microscopy, x-ray, and endoscopic examinations. This reference extensively documented many negative observations following use of a large sampling of devices. The observed damage was categorized as nicks, kinks, roughness, erosion, tears, deviations in the material, surface particles, particles found inside balloon, and multiple defects. As above, EP Catheters are subject to all of these effects (except that diagnostic catheters do not have balloons) unless appropriate validation studies are performed that would demonstrate a high degree of confidence that these catheters are able to withstand the wear and tear of repeated use, recleaning, and resterilizations. The literature indicates assurance that sterility can be safely repeated, but the presence of debris, pyrogens, mechanical changes in the device (dimensional and/or structural), etc., remain as potential problems. Each reprocessing sequence increases the chances of new or worsened nicks, kinks, roughness, erosion, tears, deviations in the materials, and/or surface particles. Further, simple continued handling

[3] "Patients in Danger: The Reuse of Single-Use Medical Devices in Europe," EUCOMED, June 2002.
[4] "Potential Reuse? A Study of the Private and Professional Reprocessing of Catheters, Guidewires, and Angioscopes," Andreas Beck, Schnetztor-Verlag GmbH, Konstanz, Germany, 2001.

(properly or improperly) of these precision instruments after each use, during reprocessing, and prior to next use could compromise the ability of these catheters to perform as originally intended by the manufacturer.

In summary, BWI believes that applications for multiple use of diagnostic EP Catheters designated as "single use" devices must be accompanied by appropriate validation data to provide objective evidence that EP Catheters may be considered safe for multiple uses (up to the number of times specified by the manufacturer or reprocessor) before they can be cleared as reprocessed or reusable devices.

Therefore, BWI recommends that Electrophysiology Catheters be included on FDA's list of devices that will require validation data to permit reuse.

We appreciate the opportunity to comment on these issues.

Sincerely yours,

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