

8 September 2000

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**Biosense Webster**  
a Johnson & Johnson company

Dockets Management Branch  
Food and Drug Administration  
Department of Health and Human Services  
Room 1061, 5630 Fishers Lane  
Rockville, MD 20854

**RE: ADDITIONAL INFORMATION REQUESTED BY FDA TO CITIZEN'S  
PETITION (DOCKET NUMBER 00P-1265/CP 2) DATED 20 AUGUST 2000**

In response to a telephone conversation held today, 8 September 2000, with Casper Uldriks, Kent Berthold, and John Glass, of the Office of Compliance, FDA, and Amy Walters and Marcia Leatham, Biosense, regarding clarification of Biosense Webster, Inc.'s (Biosense) Citizen Petition dated 20 August 2000, the following additional information and clarification is provided. We appreciate the efforts of FDA to fully understand our request prior to making a determination on it.

**Background**

In response to the final rule, dated 9 May 1997, requiring exposed connectors of certain electrode lead wires and patient cables to be protected, Biosense submitted a Citizen's Petition (docket number 00P-1265/CP 1) requesting a 60 day variance from the regulation. This Petition covered all product codes for our electrophysiology catheters and cables that terminated in 2 mm exposed tip pins. FDA granted us this variance on 9 May 2000. The extension granted allowed Biosense to complete all the work necessary to fully qualify and validate our solution for the 3 mm products, including packaging, sterilization, and aging studies. Since 9 July 2000, all products covered in this original Petition have been shipped to customers with protected tip pins.

00P-1265

Endocardial  
Diagnostics  
and Therapy

SUP 1

## Current Petition

On 17 August 2000, Biosense received a phone call from Stewart Crumpler, Office of Compliance, FDA. Mr. Crumpler called to tell us that he had spoken with one of our customer hospitals in Florida, who called on various matters, including the information that they had just received a shipment of electrophysiology products from Biosense, which terminated in an unprotected tip pin. The products at issue do terminate in an exposed plug, but they are large, 6 mm (0.25 in) Nexus “stereo headphone-type” plugs, much larger than the 2 mm tip pins covered in our previous Petition, which are already converted to protected pins.

In discussing with Mr. Crumpler why Biosense did not consider the 6 mm Nexus plugs to be subject to the performance standard, we explained that in analyzing the regulation, including the preamble, Biosense came to believe these large tip pins were not subject to the regulation. The focus of the regulation is on the ability to inadvertently insert the tip pin into a power outlet allowing unwanted energy to be transmitted to user or patient: in the final rule, FDA states that “a performance standard is needed to prevent electrical connections between patients and electrical power sources.” The performance standard was developed “to address the risk of patient exposure to macro shock or electrocution due to the inappropriate connection of a patient-connected cable or electrode lead wire to an alternating current (AC) power source.”

Biosense performed testing with the Nexus plug, including electrical creepage distance and dielectric strength (high pot), to ensure that the Nexus plug met the expressed purpose of the performance standard. Test results demonstrated that it is not possible to conduct energy from the power outlet. Additionally, as stated in our 20 August 2000 Petition, the Electrophysiology (EP) Lab is shielded – walls, floor, and ceiling, and all the equipment grounded. Any possible conducting surfaces (i.e., trays) are covered to ensure a sterile field. The patient bed is constructed from a radiopaque, polymeric, nonconducting material. All of these features create an environment in the EP lab in which protection from unwanted electrical transmission is maximized. We therefore believed that the products with Nexus plugs were exempt from the standard.

Mr. Crumpler informed us that FDA did not agree with our assessment, and that the 6 mm Nexus plugs were, indeed, subject to the regulation on the basis of the conductive surface test. We agreed to immediately seek a solution(s) for these tip pins and to implement it as quickly as possible.

This led to Biosense filing the current Petition (00P-1265/CP 2), requesting (1) a retroactive variance for all affected 6 mm products shipped since the 9 May 2000 deadline, and (2) a prospective variance, until 30 December 2000, to allow continued patient access to the catheters while Biosense identifies, qualifies, and validates a solution for the Nexus plug products. The additional time is necessary to ensure that the solution(s) identified can withstand sterilization, does not affect the packaging in an adverse way, and will maintain its integrity over the shelf life of the products.

#### **Current Status**

Biosense is proceeding with all appropriate haste to implement a solution to the exposed 6 mm Nexus plugs. Because of the differences in size and materials between the 2 mm and 6 mm tip pins, a new solution had to be identified, and will have to be fully validated before implementing on product which is to be shipped to customers and used in patients. We have made significant progress in identifying solutions, and have pilot products manufactured with one of the solutions in sterilization at this time. A second solution is being pursued in parallel, but is slightly behind the first. The products in sterilization will be tested for package and shipping integrity, and shelf life testing will begin shortly. Once all validation work is completed successfully, the solution will be implemented on products to be shipped to customers. We fully expect to have all work completed, and to have completed the transition to protected Nexus plugs across all affected product lines no later than 30 December 2000.

Hopefully, the above information fully clarifies the history and reasons for a second Citizen's Petition for a variance regarding exposed tip pins. If you have any additional questions, or need further information, please do not hesitate to contact us.

Respectfully submitted,



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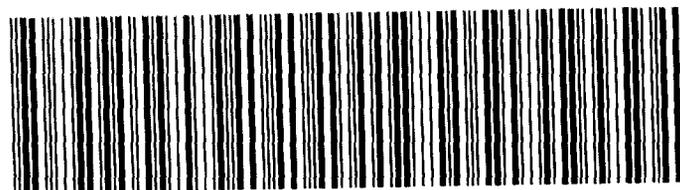
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