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**EP TECHNOLOGIES**

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Dockets Management Branch  
Food & Drug Administration  
Department of Health and Human Services  
Room 1061  
5630 Fishers Lane  
Rockville, Maryland 20857

EP Technologies, Inc.  
2710 Orchard Parkway  
San Jose, CA 95134  
408.895.3344  
www.bsci.com

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**CITIZEN PETITION**

The undersigned submits this petition under the performance standard regulation appearing in 21 C.F.R. Part 898 as authorized under Sections 501, 502, 513, 514, 531-542, 701, and 704, of the Federal Food, Drug, and Cosmetic Act 21 U.S.C. 351, 352, 353, 352,360c, 360d, 360gg-360ss, 371, 374 and 42 U.S.C. 262, 264 to request the Commissioner of Food and Drugs to grant a variance from application of the performance standard.

**Action Requested**

This petition requests a variance from the application of the Performance Standard for Electrode Lead Wires And Patient Cables regulation, which appears at 21 C.F.R. Part 898. The objective of the variance is to obtain a delay in the effective date until November 15, 2000 for some devices for the reasons described below in the Statement of Grounds.

**Statement of Grounds**

The petitioner manufactures and distributes cardiac ablation catheters, electrode recording/pacing catheters, and associated patient cabling devices. These restricted/prescription devices are used by cardiac electrophysiologists (i.e., cardiologists devoted to the diagnosis and treatment of patients with irregular heartbeats) who apply their unique skills in controlled clinical environments with the assistance of specially trained and qualified health care practitioners. The procedures for which these devices are used have been applied since 1978, and the petitioner is not aware of any adverse event for which compliance with the above referenced performance standard would have prevented the possibility of an event.

The petitioner was aware of and knowledgeable about the May 9, 2000 effective date of the performance standard. The petitioner kept abreast of health community and industry participation activities directed toward accomplishment of an orderly transition. These efforts were necessary to assure that any modifications to the design of the above referenced devices would enable the petitioner to comply with Food and Drug Administration (FDA) regulations, in particular those relating to the Quality System Regulation (QSR) and requirements for design control.

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Because there is a large number of device manufacturers of connected equipment, for which accessories may be interchanged, and because of the absence of any recognized standard for which compliance would assure compatibility, voluntary efforts to comply were initiated by health care and industry personnel. The completion of an orderly industry wide transitional process has taken longer than anticipated. These voluntary efforts occurred under the auspices of industry and began with an informal meeting of those manufacturers affected by the performance standard; namely, catheter manufacturers and electrogram recording companies. On or about May 1999, this cooperative process was completed and the criteria necessary for connected equipment device compatibility were identified. Nonetheless, it is a fact that not all recording equipment has been retrofitted to accept the consensus design for protected lead electrodes.

As a result of the necessary, but unfortunate, delay in developing consensus, not all manufacturers of connected equipment devices have been able to complete their plans for compatibility with the newly designed protected electrode lead wires and patient connection cables. Consequently, as directed in 21 C.F.R. § 898.14(a), the petitioner provides the following as the basis for its statement of grounds.

(1) Device Name, Class, and Labeling

The following devices are the subject of this variance request and representative labeling for each is provided as an exhibit:

<b>NAME OF DEVICE</b>	<b>CLASS</b>	<b>LABELING</b>
<b>Cardiac Ablation Catheters</b>	III  No C.F.R. Reference P920047	Exhibit A
<b>Cardiac Ablation System Instruments</b>	III  No C.F.R. Reference P920047	Exhibit B
<b>Diagnostic Electrode Recording and Pacing Catheters</b>	II  21 C.F.R. § 870.1220 21 C.F.R. § 870.1280 K#s 924163, 940168, 953750, 992777	Exhibit C
<b>Diagnostic Electrode Recording and Pacing Catheter Cables</b>	II  21 C.F.R. § 870.1220 21 C.F.R. § 870.1280	Exhibit D

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(2) Reason

The petitioner asks FDA to recognize that because of potential equipment incompatibility (i.e., old receptacles and new protected lead electrodes), that hospitals may not be capable of providing a safe and effective laboratory environment for their patients. This situation is unacceptable. Adapters that comply with the performance standard for the conversion of recording equipment connections are not available, due to the small size of the receptacles (spaced closely together) and numerous connections. Until all electrogram recording equipment at hospitals is retrofitted or replaced, hospitals will continue to face this dilemma. Further, adapters cannot be made to be permanently attached, by collets or tools as FDA has recommended.

Secondly, petitioner has redesigned its devices consistent with applicable procedures appearing in 21 C.F.R. Part 820 and has a limited supply of inventory to accommodate reasonable demands from users. However, the present inventory of compliant devices will be inadequate if user demand exceeds petitioner's ability to supply. A significant inventory of devices manufactured prior to May 9, 2000 is available. However, it may not be possible to complete remanufacture of these devices if user demand exceeds available supply.

To the extent that petitioner can supply devices that comply with the performance standard, it will do so and there will be no need to apply the provisions of the requested variance. However, in anticipation of the possibility that user demand may exceed the ability of petitioner to supply devices that comply with the performance standard, the petitioner seeks this variance to accommodate user needs and avoid confusion that could result from efforts by users to obtain and use other devices.

(3) Alternative Steps

In 1990, petitioner first began to make available to licensed practitioners the various prescription/restricted devices identified above. It is essential to recognize that the electrophysiology laboratory does not contain the same sources of line power that lead to macroshock injuries and electrocution deaths in other locations (e.g., neonatal intensive care). EP labs commonly relay electrogram signals from the heart or deliver externally generated pacing stimuli in DC milliamps. The petitioner believes that the design, intended use, and directions for use, which existed prior to May 9, 2000, were adequate to protect patients from the possibilities this performance standard seeks to prevent for the field of electrophysiology.

Petitioner recognizes that the user community is aware of the performance standard, but petitioner also understands that numerous petitions for exemption or variance have been directed to the FDA and that some of these petitions have been granted in whole or in part.

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Therefore, petitioner proposes to implement the following procedure during the time period of variance to assure continued safe and effective use of its devices for their intended use:

- a) If petitioner is unable to supply a device from the current inventory of devices that comply with the standard, it will promptly notify the user, and offer to provide a device which has not been remanufactured to conform to the standard, and record such notification.
- b) If the user elects to accept the petitioner's offer, a brightly colored special label containing the following text will be affixed to the device package:

“WARNING: Cables DO NOT comply with the FDA Performance Standard, 21 C.F.R. 898.

The use of catheters or cables with unprotected male pin connectors present a risk of electrical hazard. Inadvertent attachment of pin connectors to power supply sockets or connectors could result in electrocution of the patient or operator. Misconnection of the pins could also lead to inappropriate delivery of RF current through a band electrode. The users of components with unprotected male pin connectors must exercise extreme caution during device set-up to prevent patient or operator injury.”

- c) Petitioner will maintain complete records of any transactions between potential users and the petitioner relating to devices subject to the variance for review by authorized representatives of the FDA

#### **Environmental Impact**

The petitioner claims categorical exclusion pursuant to 21 C.F.R. § 25.34(c) for devices and electronic product subject to exemption or variance from a standard.

#### **Economic Impact**

Acceptance of the petitioner's request for variance will not have a material impact on the cost of devices subject to the variance, whereas denial of the request for variance could increase

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costs significantly both in time and effort wasted by hospitals that find themselves unable to treat patients with compatible electrophysiology equipment.

**Certification**

The undersigned certifies that, to the best knowledge and belief of the undersigned, this petition includes all information and views on which the petition relies, and that it includes representative data and information known to the petitioner which are unfavorable to the petition.

Signature   
Name of Petitioner Boston Scientific EP TECHNOLOGIES, Inc.  
by Steve Jwanouskos  
Mailing Address 2710 Orchard Parkway  
San Jose, CA 95134 USA  
Telephone number (408) 895-3529  
Pager number (800) 895 1670