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Dockets Management Branch
HFA-305
Food and Drug Administration
Dept. of Health and Human Services, Room 1-23
12420 Parklawn Drive
Rockville, MD 20857

RE: CLASS II 510 (k) EXEMPTION PETITION

To Whom It May Concern:

As provided for by 510 (m)(2), I wish to request an exemption to the 510(k) process with a device classification as an Accessory to an Electrode Cable (CFR 890.1175 - "Electrode Cable, ... a device intended for medical purposes to connect an electrode from a patient to a diagnostic machine"), a 510 (k) exempt device. Even if it should be classified under another, non-exempt CFR, after your review of the following, I believe the FDA will determine, "that a premarket notification ... is not necessary to assure the safety and effectiveness of the device."

My device is an extremely simple one (Figure 1). Its purpose is to provide a heretofore unavailable electrically safe connection between a standard EKG eyelet and the proximal (pin type) end of an intravascular electrode. (From the eyelet, the signal would be carried in standard fashion through an EKG patient cable to a bedside monitor (Figure 2.)) The device contains only 5 distinct components : a high impact plastic housing, a standard 2 piece (male and female) EKG eyelet, (two) pin jacks (one is electrically "blind", i.e., not connected to anything but purely meant to electrically isolate one electrode pin), a 1000 Ohm resistor and, finally, wire connecting the EKG eyelet to the resistor and the resistor to the pin jack. In essence, calling this a "device" is like calling a piece of wire connecting two electrodes a "device" (the only difference being the 1000 ohm resistor in between). Its intended use would be to facilitate placement of a temporary transvenous pacemaker or central venous catheter (CVP) by providing electrocardiographic guidance.

Electrocardiograms display the path of an electrical signal as the myocardium depolarizes and re-polarizes. Traditionally, this is detected through electrically conductive electrodes placed on the skin which in turn are connected to cables leading backwards to a monitor or electrocardiograph . There are many circumstances when an intravascular signal is preferable, particularly in the placement of internal pacemaker electrodes. One way of placing them is with EKG guidance

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(Figure 2.) : rather than seeing the *anatomic* position as one would with fluoroscopy, one sees the “*electrical*” position by viewing the signal carried retrograde from the pacer electrode. (This signal changes as the electrode moves from the subclavian vein/ superior vena cava to the right atrium to the right ventricle, finally abutting the endocardial (inner) surface of this ventricle.) To the present time, given the “pin” shape of the proximal end of an intravascular electrode and the “nipple” shape of an eyelet-type electrode, there has been no electrically stable or safe method available to connect an EKG cable to this intravascular electrode. My device provides such a connection by providing a standard EKG eyelet wired to a pin jack (which accommodates the pin leading from the intravascular electrode). The EKG cable would be attached to this eyelet and function in the usual way. Additionally, as most EKG signals are received through some resistance (e.g., from an electrode attached to skin), a resistor is placed in series between the EKG eyelet and pin jack to “replace” the resistance absent from an intravascular source. Once it appears that the pacemaker electrode has been correctly placed, it would be disengaged from my device and connected to a pulse generator for pacing.

Another similar use for this device would be in the placement of a CVP catheter. Correct positioning of such a catheter is just above the level of the right atrium, in the distal superior vena cava. If an electrode were placed at the tip of this catheter, the electrical transition from superior vena cava to right atrium is generally obvious. Appropriate placement then could be established without waiting (as is the current practice) for a chest x-ray, avoiding the risks of re-positioning, disrupting the sterile field at the insertion site, etc..

The requirements for this exemption as stipulated in 510 (m)(2) are:

“(1) The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials ... ;
(2) characteristics of the device necessary for its safe and effective performance are well established;
(3) changes in the device that could affect safety and effectiveness will either: (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm..., or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment; and,
(4) any changes to the device would not be likely to result in a change in the device's classification.”

Specifically addressing these issues:

1) “The device does not have a significant history of false or misleading claims or of risks associated with inherent characteristics of the device, such as device design or materials ...”.

This device is new (Patent # 5,666,958) and therefore has no such history. However, electrical connectors are commonplace in all aspects of medical care, most of far greater complexity than the present one. The manufacturer's specifications for the pin jacks and EKG eyelets are included. As all components are playing a purely passive role, i.e., conducting an electrical signal away from the patient, and no power source of any kind is used when the device is being used, there is no

risk whatsoever associated with its use.

(2) "Characteristics of the device necessary for its safe and effective performance are well established".

Again, the two major components of this device, i.e., the EKG eyelet and the pin jack, have been in use and standardized for decades. Likewise, the 1000 ohm resistor and the two connecting wires are universally found and standardized. Countless medical devices (including many 510 (k) exempt) depend on them in any number of combinations for their proper function. This is a connection - in - series in its simplest form.

(3) "Changes in the device that could affect safety and effectiveness will either: (a) be readily detectable by users by visual examination or other means such as routine testing, before causing harm..., or (b) not materially increase the risk of injury, incorrect diagnosis, or ineffective treatment".

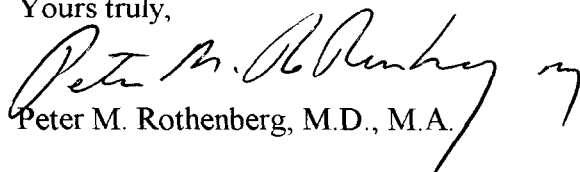
The sole purpose of this device is to facilitate placement of an electrode / catheter by permitting the display of an intravascular signal on a bedside monitor. Failure of the device would be obvious immediately as a waveform would not be seen. Even if the device failed during placement, both temporary transvenous wires and CVP's currently are routinely placed "blind", without electrical or fluoroscopic guidance. Use of this device confers no additional risk of injury above that inherent in the placement procedure itself. (To the contrary, it shortens the procedure generally by over 50% and avoids use of fluoroscopy and any risk of this radiation.) In the event of total failure, one would be left with current standard of care. "Incorrect diagnosis or ineffective treatment" are not possibilities.

(4) "Any changes to the device would not be likely to result in a change in the device's classification."

This device is purely designed to permit the connection between two specific and dissimilarly shaped electrodes. Its design necessarily limits its extension to other applications. Any changes sufficient to warrant a change in classification would essentially entail creating a new device.

I will look forward to your decision.

Yours truly,


Peter M. Rothenberg, M.D., M.A.