



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 16 2008

Remington Medical, Inc.
c/o Mr. Don Rosvold
6830 Meadowridge Court
Alpharetta, GA 30005

Re: K971968

Trade/Device Name: Safe Connect Surgical Cable
Regulation Number: 21 CFR 870.5550
Regulation Name: Patient transducer and electrode cable (including connector)
Regulatory Class: II
Product Code: DSA
Dated (Date on orig SE ltr): July 23, 1997
Received (Date on orig SE ltr): May 28, 1997

Dear Mr. Rosvold:

This letter corrects our substantially equivalent letter of July 23, 1997.

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

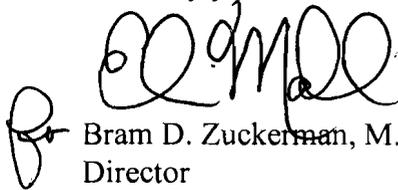
Page 2 - Mr. Don Rosvold

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to continue marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address <http://www.fda.gov/cdrh/dsma/dsmamain.html>

Sincerely yours,

A handwritten signature in black ink, appearing to read "Bram D. Zuckerman". The signature is written in a cursive style with a large initial "B" on the left.

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

510(k) Number (if known): K971968

Device Name: Safe Connect Surgical Cable

Indications For Use:

The Remington Medical Disposable Surgical Extension Cable is an electrical extension cable used to transmit signal from, or power or excitation signal to patient-connected electrodes. The cable is bipolar, providing alligator clips at the end of the cable that will be attached to the patient's lead, and a safety plug at the other end that allows electrical connection to the external pacemaker or testing device (i.e. analyzer). The alligator clips are color coded and imprinted with the polarity: The red clips are positive (+) and the black clips are negative (-).

The cable is designed to carry a maximum electrical load of 300 volts, and will be compatible with most external pace makers, pace analyzers, and patient pacing leads currently on the market.

The cable is a sterile, disposable device.

(PLEASE DO WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christy Foreman per AAC
(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K971968

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)

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