JAN 2 8 2004

510(k) Summary of Safety and Effectiveness

Submitter:	Sontra Medical Corporation 10 Forge Parkway Franklin, MA 02038
Contact Person:	Albert Farinha Director of Clinical and Regulatory Affairs Telephone: 508-553-8850 x224 Fax: 508-553-8720 sfarinha@sontra.com
Date:	January 11, 2004
Trade Name:	SonoPrep™ Impedance Diagnostics (IDx)
Common Name:	Electrocardiograph (ECG) Electrode
Classification Names and References:	Cardiovascular Monitoring Devices, 21 CFR 870.2360, Electrocardiograph Electrode.
Predicate Device:	Quinton, Inc. QuikPrep Electrode System, K782079
Device Description:	The Sontra Medical Corporation SonoPrep™ Impedance Diagnostics (IDx) System consists of a microprocessor controlled ultrasonic skin prep generator, a reusable handpiece, a reusable handheld contact electrode, coupling media and ECG electrodes used for ultrasonically treating intact skin in order to lower the skin impedance for the application of ECG electrodes for monitoring heart rates.
Intended Use:	Use of these products is indicated for the preparation of intact skin to lower skin impedance. The supplied electrodes are intended to be used for ECG monitoring.
Technological Characteristics:	The SonoPrep IDx system uses low level ultrasonic energy to create cavitation in a coupling solution which results in the cavitation in the handpiece that causes the outermost layer of skin, the *stratum corneum*, to become increasingly

	conductive. The increased conductance or lower impedance improves the signal to noise ratio which is important in ECG monitoring.
Performance Data:	Bench testing, clinical testing and biocompatibility data demonstrate that the device is comparable to previous cleared devices. Clinical studies showed no difference in ECG waveform morphology or long term impedance as compared to the predicate device. Some patients developed redness at the treated sites which resolved within 24 hours and required no further follow-up treatment.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Sontra Medical, Inc.
c/o Mr. Albert Farinha
Director of Regulatory and Clinical Affairs
58 Charles Street
Cambridge, MA 02141

Re: K023713
Trade Name: SonoPrep™ Impedance Diagnostics (IDx) System
Regulation Number: 21 CFR 870.2370
Regulation Name: Electrocardiograph Surface Electrode Tester
Regulatory Class: Class II (two)
Product Code: KRC
Dated: November 4, 2003
Received: November 7, 2003

Dear Mr. Farinha:

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 application (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 such 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.

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 begin 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 (301) 594-4646. 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 (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

Donna R. Zuckerman

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Attachment 3 – Statement of Indications for Use

510(k) Number: K023713

Device Name: Sontra Medical Corporation SonoPrep™ Impedance Diagnostics (IDx) System

Intended Use / Indications for Use:

The Sontra Medical Corporation SonoPrep™ Impedance Diagnostics (IDx) System is intended to be used for preparation of intact skin to lower skin impedance. The supplied electrodes are intended to be used for ECG monitoring. Clinical results demonstrated that the SonoPrep IDx reduced skin impedance for 24 hours when used in conjunction with the supplied ECG electrodes; with some patients developing skin irritation. However, any skin irritation resolved within a 24 hour period.

Environment of Use / Patient Population:

Handpiece: For multiple patient use in physician's office or hospital/institutional environment.

Electrodes: For single patient use on adult patients (>30kg).

(PLEASE DO NOT WRITE BELOW THIS LINE/CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Donna R. Heckman

Division of Cardiovascular & Respiratory Devices
510(k) Number K023713

Prescription Use X
(per 21 CFR 801.109)

OR

Over the Counter Use ___