

AUG 17 2004

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**SUMMARY OF SAFETY AND EFFECTIVENESS**

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**510(k) Summary of Safety and Effectiveness**

Information supporting claims of substantial equivalence, as defined under the Federal Food, Drug and Cosmetic Act, respecting safety and effectiveness is summarized below. For the convenience of the Reviewer, this summary is formatted in accordance with the Agency's final rule "...510(k) Summaries and 510(K) Statements..." (21 CFR 807) and can be used to provide a substantial equivalence summary to anyone requesting it from the Agency.

**MODIFIED DEVICE NAME:** SonoPrep<sup>®</sup> Ultrasonic Skin Permeation System and Procedure Tray

**EXISTING DEVICE NAME:** SonoPrep<sup>®</sup> Impedance Diagnostics (IDx) System

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**510(k) SUMMARY**

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**Predicate Devices**

The Sontra Medical, SonoPrep<sup>®</sup> Impedance Diagnostics (IDx) System, K023713 and the Norwood Abbey, LAD-01, K021222, were selected as the predicate devices for this submission.

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**Device Description**

The SonoPrep<sup>®</sup> Ultrasonic Skin Permeation System is a portable battery operated reusable device that disrupts the stratum corneum layer of the skin by means of cavitation of a fluid with ultrasonic energy. The result of the treatment allows the rapid onset of topical OTC lidocaine 4%.

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**Intended Use**

The SonoPrep<sup>®</sup> Ultrasonic Skin Permeation System and Procedure Tray is indicated for the disruption of the outer layer of skin prior to the application of OTC topical 4% lidocaine cream, for local dermal anesthesia prior to a needle insertion or IV procedure.

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**Indications Statement**

The SonoPrep<sup>®</sup> Ultrasonic Skin Permeation System is indicated for the rapid production of local dermal anesthesia using topical OTC lidocaine 4%.

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**Technological Characteristics**

The SonoPrep<sup>®</sup> Ultrasonic Skin Permeation System is technologically identical to the predicate device. Changes include modified materials, a disposable procedure tray and expanded indications for use.

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510(k) Summary of Safety and Effectiveness Continued

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**Performance Data**

Laboratory and bench top evaluations have determined that the modifications comply with design requirements and meet or exceed the original design. An IRB approved randomized, controlled study was conducted involving 320 subjects. Full needle insertion of a 23G 5/8" needle was used as a standard pain stimulus. After treatment and needle insertion subjects were asked to rate the pain using an accepted pain evaluation scale; pain scores were tested and analyzed per the approved protocol.

Results demonstrated that the SonoPrep<sup>®</sup> Ultrasonic Skin Permeation System can produce a rapid dermal anesthetic effect using topical OTC lidocaine 4%.

Analysis of clinical observations from 320 subjects taken approximately 24 hours after treatment revealed no adverse events or significant skin irritation due to the treatment.

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**Conclusion**

Based on the 510(k) summaries and the 510(k) statements (21 CFR 807) and the information provided herein, we conclude that the new device is substantially equivalent to the Predicate Device under the Federal Food, Drug and Cosmetic Act.

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**Contact**

Albert Farinha  
Director, Operations and Regulatory Affairs  
Sontra Medical Corporation  
10 Forge Parkway  
Franklin, MA 02038

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**Date**

August 13, 2004



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

AUG 17 2004

Mr. Albert Farinha  
Director of Operations and Regulatory Affairs  
Sontra Medical, Inc.  
10 Forge Parkway  
Franklin, Massachusetts 02038

Re: K040525

Trade/Device Name: Sontra Medical Corporation SonoPrep® Ultrasonic Skin  
Permeation System and Procedure Tray

Regulation Numbers: 21 CFR 878.4410, 21 CFR 878.4810

Regulation Names: Low energy ultrasound wound cleaner, Laser surgical instrument  
for use in general and plastic surgery and in dermatology

Regulatory Class: II

Product Code: NRJ

Dated: June 18, 2004

Received: June 21, 2004

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 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). You may, therefore, market the device, subject to the general controls provisions of the Act. However, you are responsible to determine that the medical devices you use as components in the tray have either been determined as substantially equivalent under the premarket notification process (Section 510(k) of the act), or were legally on the market prior to May 28, 1976, the enactment date of the Medical Device Amendments. Please note: If you purchase your device components in bulk (i.e., unfinished) and further process (e.g., sterilize) you must submit a new 510(k) before including these components in your tray. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, and labeling, and prohibitions against misbranding and adulteration.

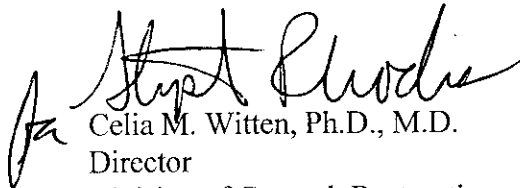
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further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

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 the labeling regulation, please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and "W".

Celia M. Witten, Ph.D., M.D.

Director

Division of General, Restorative  
and Neurological Devices

Office of Device Evaluation

Center for Devices and Radiological Health

16040525

### Indications for Use

510(k) Number (if known): K040525

Device Name: Sontra Medical Corporation SonoPrep® Ultrasonic Skin Permeation System and Procedure Tray

Indications For Use:

The Sontra Medical Corporation SonoPrep® Ultrasonic Skin Permeation System and Procedure Tray is indicated for the temporary disruption of the outer layer of skin prior to the application of OTC Topical 4% Lidocaine Cream, for local dermal anesthesia prior to a needle insertion or IV procedure.

Prescription Use    
 (Part 21 CFR 801 Subpart D)

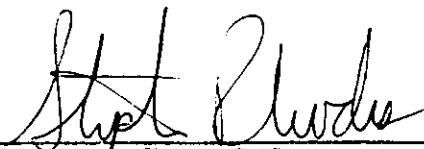
AND/OR

Over-The-Counter Use \_\_\_\_\_   
 (21 CFR 807 Subpart C)

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

  
\_\_\_\_\_  
(Division Sign-Off)  
**Division of General, Restorative,  
and Neurological Devices**

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