

K980784

APR 29 1998

510(k) Summary

Submission: Sahar Technologies, Inc.

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San Diego, CA 92123 USA

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Contact: Gary Shaffer

Date: 1/20/98

Trade name: SureTouch

Common name: Laser scanner

Regulatory class: II

Product code: GEX

Substantial equivalence claimed to:

1. Sahar Technologies Inc. SoftScan; 510(k) number K971024
2. Sahar Technologies Inc. SofTouch; 510(k) number K964684
3. Clinicon Corporation SureScan; 510(k) number K962242
4. Lasersonics Parascan; 510(k) number K955734

Description:

Adding the SureTouch to a laser will convert the system into a sophisticated, easy to use aesthetic surgery tool that can perform the widest range of cosmetic procedures. SureTouch may be used for a variety of soft tissue ablation procedures, including aesthetic laser surgery where layer by layer of micro-ablation is required. SureTouch introduces an extra dimension of control for precise tissue removal. The SureTouch aiming beam mode visually displays the area about to be treated on the tissue. While watching the aiming beam, the physicians can change the shapes and sizes. The aiming beam outline will change, continuously displaying the area that is about to be treated.

Filling in the displayed area is performed using a precise microprocessor control motion that deflects the laser beam on the tissue to ensure maximum accuracy and homogeneity. The SureTouch coordinates the laser emission while leaving the physician in full control of laser output at all times.

Intended use:

Treating large and variable areas of soft tissue on the skin with a laser requires a device that can manipulate and place the pulsed or CW emission in a safe and consistent manner. The SureTouch provides the means to cover small and large areas of skin tissue with precise control of the emission placement. The ability of the physician to identify the area to be treated by watching the aiming beam, while controlling the shape and size that best fits the treated area enhances the precision and safety of the treatment. A variety of dermatological applications are enhanced by the precise control of laser emission the SureTouch enables. SureTouch will be used to manipulate and place a pulsed and/or CW laser beam for use in dermatological applications including ablation, vaporization, and coagulation of soft skin tissue.

Summary of technological characteristics:

Technologically, the SureTouch Scanning System offers all of the features and functionality of the Sahar Technologies SoftScan and SofTouch scanning systems. The SureTouch offers greater flexibility than other scanning systems in terms of different wavelength specific applications.

Microprocessor controlled scanning systems, in general, bring improved safety to the laser marketplace due to the increased control, precise placement, and homogeneous application of laser energy. The SureTouch Scanning System utilizes a hand-held device that is flexible enough to allow the physician the freedom to choose the area of treatment without being restricted by the system.

The SureTouch improves safety by decreasing fatigue experienced by the physician caused by the normally tedious nature of applying single spot laser energy over large areas.

The improved performance of the SureTouch device allows for better fluence at lower power levels, which is also a net increase in safety.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Gary Shaffer
•Regulatory Affairs Manager
Sahar Technologies, Incorporated
3940 Ruffin Road, Suite C
San Diego, California 92123

Re: K980784
Trade Name: SureTouch
Regulatory Class: II
Product Code: GEX
Dated: January 20, 1998
Received: March 2, 1998

Dear Mr. Shaffer:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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. 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.

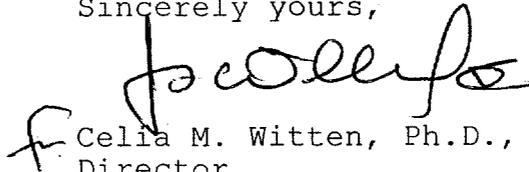
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

Page 2 - Mr. Shaffer

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K 980784

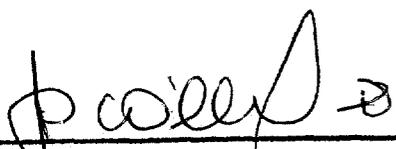
Device Name: SureTouch

Indications for Use:

SureTouch will be used to manipulate and place a pulsed and/or CW laser beam for use in dermatology for treatment of any soft tissue, including ablation, vaporization, and coagulation of soft tissue on the skin.

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices

510(k) Number

K980784

Prescription Use

OR

Over-the-Counter Use