K013751

Ein Unternehmen der Silicon Sensor Gruppe

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FEB 0 6 2002

510(k) SUMMARY
of
SAFETY and EFFECTIVENESS

A. General Information

1.	*Submitter's Name:*	Silicon Instruments, GmbH
2.	*Address:*	Ostendstrasse 1 Berlin, D-12459 Germany
3.	*Telephone:*	49-3-06-39-92-360
4.	*Contact Person:*	Dr. Thomas Goebel
5.	*Date Prepared:*	October 29, 2001
6.	*Registration Number:*	FDA Form 2891 Submitted

B. Device

1.	*Name:*	SI-Handheld Gamma Finder (HGF)®
2.	*Trade Name:*	Handheld Gamma Finder
3.	*Common Name:*	Nuclear Uptake Probe
4.	*Classification Name:*	Probe, Uptake, Nuclear
5.	*Product Code:*	IZD
6.	*Class:*	I
7.	*Regulation Number:*	892.1320

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Amtsgericht
AG Berlin-Charlottenburg
HRB 68092
Geschäftsführer: Dr. Bernd Kriegel

Deutsche Bank Berlin

C. Identification of Legally Marketed Devices

1. *Name:* Neoprobe Model 1500
2. *K Number:* K971167
3. *Date Cleared:* June 26, 1997

D. Description of the Device

The gamma-detector, energy discriminator, amplifier, controls and energy supply have been assembled into a single hand-held unit SI-Handheld Gamma Finder® (HGF), which is shielded by a biocompatible polymer. The probe's shape is conical; its shaft tapers off towards a tip that holds the collimator, the crystal and the PIN-diode while a head of larger diameter houses the display, menu buttons, and other components. The device is held in one hand by the middle of the shaft. Outer diameters and weight are designed so as to allow single-handed use over periods of time longer than those of routine sentinel biopsies. The polymer casing of SI HGF is water resistant and thus allows extended cleansing with commercial surface disinfectants. The probe tip may even be immersed in disinfectants for several hours. This fulfills standard requirements of hospital hygiene. Disinfection of the probe is comparable to other, larger probes that are being used like Gamma Finder in conjunction with disposable sterile plastic covers.

The HGF can be switched on or off by any key. Results are numerically shown in the liquid crystal display in counts per second (CPS), and updated every second. The HGF has only four keys:

E. Latest Valve Measured

F. Acoustic Signal ON/OFF in menu mode (+)

G. LED ON/OFF in menu mode (−)

H. Menu Mode ON/OFF

- 1x Sub-menu dynamics
- 2x Sub-menu volume (Six levels)
- 3x Menu Mode off

The currently measured value can be retained in the display for 5 seconds by pressing Key A.

The HGF is packaged and transported in a small suitcase, see Appendix A for a photograph.

The HGF can only be operated by a Sonnenschein Lithium Battery (SL2770/T), with a maximum charging current of 15 mA. It is not user replaceable. The display of the HGF will display an battery symbol, warning the user the battery life is approximately 20 hours from exhaustion. If the battery is exhausted, the display will show "LobAt".

Battery Information is located in Appendix B.

The only accessory is a Sterile Sleeve (No. SI–FOL–101) that accompanies each device, along with the User Manual.

E. Intended Use Statement

The HGF is a measuring instrument for preoperative and intraoperative detection of radioactive substances in the energy range between 140 keV and 360 keV (e.g. TC-99M and I-131).

It is contraindicated in dosimetric applications, detection of radiation other than gamma and detection of radiopharmaceuticals with radiation energies outside the range of 140keV – 360 keV.

F. Technological Characteristics Summary

The HGF is substantially equivalent to the Neoprobe Model 1500, cleared on June 26, 1997 as K971167.

Each nuclear uptake probe and accessories is compact, operates on an internal battery; is software or micro-controller controlled, and intended to detect and quantify gamma radiation. Both the Neoprobe Model 1500 and HGF are indicated for external and intraoperative detection of radioactivity.

The HGF was tested to the appropriate electrical standards, biocompatibility, and sterilization standards. In addition, verification testing was conducted by a university as to both system and technical evaluations.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

FEB 0 6 2002

Dr. Thomas Goebel
Head of Senior Technology
Silicon Instruments GmbH
OstendstraBe 1
D-12459, Berlin
GERMANY

Re: K013751
Trade/Device Name: SI-Handheld Gamma Finder®
Regulation Number: 21 CFR 892.1320
Regulation Name: Nuclear uptake probe
Regulatory Class: I
Product Code: 90 IZD
Dated: October 29, 2001
Received: November 13, 2001

Dear Dr. Goebel:

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 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 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 one of the following numbers, based on the regulation number at the top of this letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

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 Part 807.97). Other general information on your responsibilities under the Act may be obtained 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,

Nancy C. Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) Number: K013751

Device Name: SI – Handheld Gamma Finder

Indications for Use:

- The SI Handheld Gamma Finder is indicated to detect and quantify the gamma photons in the body intra-operatively or extra-operatively, when gamma emitting radiopharmaceuticals are administered into the human body.

PLEASE DO NOT WRITE BELOW THIS LINE –
CONTINUE ON ANOTHER PAGE IF NEEDED

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR OVER-THE-COUNTER USE ____
(optional Form 1-2-96)

David G. Hyams

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K013751