K980001

APPENDIX E

MAR 19 1998

510(k) SUMMARY

JENOPTIK L.O.S.
JENASCAN

This 510(k) summary of safety and effectiveness for the Jenoptik JENASCAN is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant:	JENOPTIK, L.O.S., GmbH
Address:	Goschwitzer Str. 25 D-07739 Jena Germany +49 3641 65 3582 +49 3641 65 3667 (Fax)
US Contact Person:	Mr. William T. Kelley 23832 Via Monte Coto De Caza, CA 92679-4001
Telephone:	714-589-8536 714-589-6259 (Fax)
Preparation Date:	December 1997
Device Trade Name:	JENASCAN
Common Name:	Scanner - an accessory to surgical lasers, especially for use in dermatology and plastic surgery.
Classification Name:	None - the scanner has not been classified as a separate device - it is an accessory to surgical lasers, e.g., general and plastic surgery and dermatology (see: 21 CFR 878.4810). Product Code: GEX.
Legally marketed predicate devices:	SofTouch Scanning Device (Sahar Technologies and Skinscan (Candela Corporation).
Description of Device:	The Jenoptik JENASCAN is a microprocessor-controlled accessory for lasers used in dermatology and plastic surgery. The JENASCAN

guides the laser energy over the skin during removal of soft tissue under the conditions of labeling as described in the laser operator's manual .

Intended Use:

The JENASCAN is intended for use as an accessory to lasers used in dermatology and plastic surgery under condition of use as described in the manuals accompanying the laser.

The following is from the Indications for Use Statement for the JENASCAN (APPENDIX B):

The JENASCAN is intended for use as an accessory to surgical lasers, e.g., lasers used in dermatology and plastic surgery, for the ablation and vaporization of soft tissue under conditions of use as described in the manuals accompanying the lasers.

Please refer to the application, operator's, or user's manual(s) accompanying the laser for professional use instructions and detailed use information concerning the laser.

Performance Data:

None. The specifications and intended uses of the Jenoptik JENASCAN are the same or very similar to those of the claimed predicate devices. There are no significant differences between the devices under conditions of intended use.

Because of this, performance data were not required.

CONCLUSION:

Based on the foregoing and other information in this application, Jenoptik, L.O.S. believes that the JENASCAN is substantially equivalent to legally marketed predicate devices, i.e., SofTouch Scanning Device (Sahar Technologies) and SureScan (Clinicon Corporation).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 19 1998

JENOPTIK, L.O.S. GmbH
c/o Mr. William T. Kelly
23832 Via Monte
Coto De Caza, California 92679-4001

Re: K980001
Trade Name: JENASCAN
Regulatory Class: II
Product Code: GEX
Dated: January 2, 1998
Received: January 2, 1998

Dear Mr. Kelly:

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 (Premarket 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.

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,

for 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

APPENDIX B

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K980001

Device Name: Jenoptik JENASCAN Scanner

Indications For Use Statement:

The JENASCAN is intended for use as an accessory to surgical lasers, e.g., lasers used in dermatology and plastic surgery, for the ablation and vaporization of soft tissue under conditions of use as described in the manuals accompanying the lasers.

Please refer to the application, operator's, or user's manual(s) accompanying the laser for professional use instructions and detailed use information concerning the laser.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use X OR Over-The-Counter Use _____
(Per 21 CFR 801.109)

Stephen Rhodes

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K980001

030