

AUG 6 1998

K982295

## 510 (k) Summary

Name: Submitter: Nidek Incorporated  
Address: 47651 Westinghouse Drive  
Fremont, CA. 94539-7474  
Phone Number: (510) 226-5700, (800) 226-5750  
Fax Number: (510) 226-5750  
Contact person: Ken Kato  
Date Prepared: June 30, 1998  
Trade Name: LightScan  
Common Name: Laser Accessory  
Classification: Class II

Substantial Equivalence Claimed to: Sahar Technologies, Inc. SoftScan 510(k) Number K971024

### Description:

Adding the LightScan to any laser will convert the system into an easy to use aesthetic surgery tool that can perform the widest range of cosmetic procedures. LightScan may be used for a variety of soft tissue ablation, vaporization and coagulation of soft tissue on the skin, including aesthetic laser surgery where layer by layer of micro-ablation is required. LightScan introduces an extra dimension of control for precise tissue removal using lower power than previously thought possible. The LightScan aiming beam makes visually displays the area about to be treated on the tissue. While watching the aiming beam, the physician can change the shapes and sizes he selects to use. The aiming beam outline will change in a concurrently to continuously display the area that is about to be treated.

Filling the area is done using a precise computer control motion that deflects the laser beam on the tissue to ensure maximum accuracy and homogeneity. Coordinating the laser emission is done by LightScan while leaving the physician in full control of laser emission at all times.

### Intended Use:

Treating soft tissue on the skin with a laser requires a device that can manipulate and place the pulsed or CW emission by covering large and variable areas in a safe and consistent way. The LightScan provides the ability to cover small and large area of soft tissue on the skin while having 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 will enhance the precision and safety of the treatment. The timing of the emission placement on the skin is done by the LightScan hardware and software to avoid errors and to increase precision

and homogeneity. LightScan is 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 laser systems. LightScan 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 tissue on the Skin.

#### Summary of the Technological Characteristics:

Technologically, the LightScan Scanning System offers all of the features and functionality of the Sahar Technologies SoftScan, Nidek CyberScan and LaserSonic's ParaScan, which all offer features and functionality in excess of the Coherent CPG. The LightScan offers a greater flexibility than the most others in terms of different wavelength specific applications.

Microprocessor controlled scanning systems in general bring improved safety to the laser applications due to the increased control, precise placement, and homogeneous application of laser energy.

Because of the normally tedious nature of applying single spot laser energy over large area, the LightScan improves safety by decreasing fatigue experienced by the physician during a procedure. The high bandwidth design of the LightScan system offers scanner capabilities previously unavailable in any applications other than CO2 laser soft tissue, extending the safety and effectiveness improvements to a broader range of procedures.

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



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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Mr. Ken Kato  
Nidek, Inc.  
47651 Westinghouse Drive  
Fremont, California 94539-7474

Re: K982295  
Trade Name: Nidek LightScan  
Regulatory Class: II  
Product Code: GEX  
Dated: June 30, 1998  
Received: July 1, 1998

Dear Mr. Kato:

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.

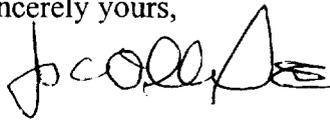
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,

  
f 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

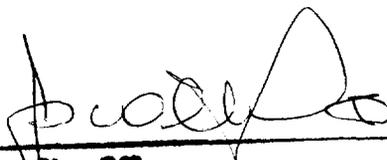
510(k) Number (if known): K982295

Device Name: Nidek LightScan Device

**Indications For Use:** The LightScan accessory device is intended to 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 K982295  
510(k) Number \_\_\_\_\_

Prescription Use  \_\_\_\_\_  
(Per 21 CFR 801.109)

OR

Over-The-Counter Use \_\_\_\_\_

(Optional Format 1-2-96)