

K 990 119

JUL 27 2000

Appendix C
510(k) Summary Statement of Safety and Effectiveness

I General Information

Submitter: Nidek Incorporated
47651 Westinghouse Drive
Fremont, California 94539-7474

Contact: Mr. Jerry Tsutsumi
Regulatory/Quality Manager

Date of Application: 10 January 1999

II Device Name

Trade/Proprietary Name: Epi-Star Diode Surgical Laser System
Model Number: Epi-Star

Classification Name: Laser Instrument, Surgical, Powered
Common Name: Diode Surgical Laser

Device Classification: Class II Medical Device
Product Code: GEX
Regulation: 21 CFR 878.4810

III Predicate Devices

The Epi-Star CO2 Laser System is substantially equivalent to the following currently marketed devices:

<u>Manufacturer</u>	<u>Product Model</u>	<u>510(k) Number</u>	<u>Decision Date</u>
• Nidek Inc.	DioLight 60	K981447	5 June 1998
• Coherent/Palomar	LightSheer	K98420	4 May 1998
• Sharplan Lasers	EpiTouch ALEX	K973354	4 December 1997
• Candela Corp.	GentleLASE	K981351	13 July 1998
• Cynosure Inc.	Photogencia LPIR	K971737	8 August 1997

IV Product Description

The Nidek Epi-Star Surgical Laser System consists of a moveable console containing power supplies, aiming and treatment lasers on a solid optical rail, and a cooling mechanism to dissipate the heat generated by the system. A touch key pad control panel with alphanumeric displays that enables the user to control the laser systems operating parameters. The Epi-Star Surgical Laser System is a "Long Pulse Diode Laser" which operates at a wavelength of 800 nm, using a Near Infrared Diode Laser Array lasing medium. The system uses a separate laser diode for its aiming beam (635 nm) and the system has a Fluence Range of up to 50 Joules/cm², variable Frequency Range (Repeat Rate) up to 15 Hz, and variable Pulse Width (Pulse Duration) up to 100 msec. More details are provided in Appendix D.

V Indications for Use

The Epi-Star Surgical Laser System is for Plastic Surgery and Dermatology, intended use for the treatment of vascular and pigmented lesions in dermatology, and for the removal of hair.

VI Performance Standards

The Nidek Incorporated Epi-Star Diode Surgical Laser System is manufactured and designed to comply with the requirements defined in Title 21 CFR 1040.10 and 1040.11, FDA regulations for Medical Laser Products, as applicable.

VII Clinical Performance Data

None presented. The specifications and indications for use for the Epi-Star Diode Surgical Laser System are the same or very similar to those of the claimed predicate devices. The Epi-Star Diode Surgical Laser System has the same indications for use for which the claimed predicates have been cleared and has no additional indications for use.

VIII Non-Clinical Performance Data

None presented.

IX Rational for Substantial Equivalence

Comparison of system specifications between the Nidek Epi-Star Diode Surgical Laser System and the Nidek Dio-Light 60 Diode Surgical Laser System (K981447) are exactly the same, except for the intended use for hair removal. As both of these systems are the same in their methods of operation and physical construction, and both systems utilize the same design, functional, and performance features (as demonstrated in Appendix B), and are therefore substantially equivalent.

Comparison of system specifications and features of the Nidek Epi-Star Diode Surgical Laser System and the other legally marketed predicate devices demonstrates the systems to be equivalent. The systems compared all have the same or similar design, functional, and/or performance features (as demonstrated in Appendix B, Substantial Equivalence Comparison), and are therefore substantially equivalent.

Since the Nidek Epi-Star Diode Surgical Laser System is substantially equivalent with respect to the indications for use, design, methods of operation, physical construction, functional and performance features to other predicated devices, we believe that this device clearly meets the requirements for substantial equivalence according to the 510(k) guidelines. The Safety and Effectiveness are reasonably assured, and therefore justifying 510(k) Premarket Notification Clearance for commercial sale and distribution.

X Safety and Effectiveness

The information provided in Appendix B demonstrates that the Nidek Inc. Epi-Star Diode Surgical Laser System is safe and effective, when indicated for use for general and specific applications in the medical specialties of dermatology and plastic surgery as describe above in Section V.

Appendix D "DEVICE DESCRIPTION" provides information regarding the systems control features and safety features designed into this product to ensure it safe use.

Appendix E provides information on the product development processes used to ensure the products safety and effectiveness during the design process.

XI Conclusion

Thus, with the information provided in this 510(k) Submission, the Nidek Epi-Star Diode Surgical Laser is felt to be substantially equivalent to other similar currently marketed predicate devices. Based on the information provided in Appendix B of this submission, the differences noted in the various products compared DOES NOT pose any new, significant effects on the safety, performance, use or effectiveness of the Epi-Star Diode Surgical Laser System. Thus, the Safety and Effectiveness of this product is reasonably assured for use in hair removal.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUL 27 2000

Nidek, Inc.
c/o Ms. Carol L. Patterson
Patterson Consulting Group
21911 Erie Lane
Lake Forest, California 92630

Re: K990119
Trade Name: Epi-Star Diode Surgical Laser System
Regulatory Class: II
Product Code: GEX
Dated: April 28, 2000
Received: May 3, 2000

Dear Ms. Patterson:

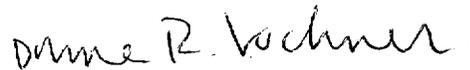
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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,



 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

Enclosure

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number (if known): K990119

Device Name: Nidek Inc. Epi-Star Laser System

Indications for use: The Epi-Star Surgical Laser System is intended to be used for Plastic Surgery and Dermatology, with the intended uses for the treatment of vascular and pigmented lesions in dermatology, and for the removal of hair.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Dan R. Vochner.
(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K990119

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