

K980475

DEC 16 1998

**SUMMARY OF SAFETY AND EFFECTIVENESS
NIDEK UNIPULSE CO2 SURGICAL LASER SYSTEM**

REGULATORY AUTHORITY:

Safe Medical Devices Act of 1990, 21 CFR 807.92

COMPANY NAME/CONTACT:

Ken Kato
Vice President
47651 Westinghouse Drive
Fremont, CA 94539
Phone: (510) 226-5700
Fax: (510) 226-5750

DEVICE TRADE NAME:

UniPulse CO2 Laser System

DEVICE COMMON NAME:

CO2 Surgical Laser System

DEVICE CLASSIFICATION:

CO2 laser systems are classified as Class II.

PERFORMANCE STANDARDS:

The laser systems manufactured by Nidek Inc. comply with 21 CFR 1040.10 and 1040.11, FDA regulations for medical laser products, as applicable.

INDICATIONS FOR USE STATEMENT:

Nideks UniPulse CO2 Laser System is intended for all cleared Coherent CO2 skin resurfacing applications.

COMPARISON WITH PREDICATE DEVICE:

The Nidek CO2 system is substantially equivalent to Coherent's CO2 laser system.

The risks and benefits of the Nidek UniPulse CO2 are comparable to the predicate device when used for similar clinical applications.

Since the Nidek UniPulse CO2 laser system is substantially equivalent with respect to indications for use, materials, method of operation and physical construction to the predicate device, we believe it clearly meets the requirement for substantial equivalence according to 510(k) guidelines. Safety and effectiveness are reasonably assured, therefore justifying 510(k) clearance for commercial sale.



DEC 16 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Ken Kato
Vice President of Administration
Nidek, Incorporated
47651 Westinghouse Drive
Fremont, California 94539

Re: K980475
Trade Name: UniPulse CO₂ Surgical Laser System
Regulatory Class: II
Product Code: GEX
Dated: November 30, 1998
Received: December 1, 1998

Dear Mr. Kato:

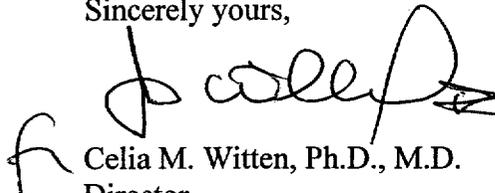
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large initial "C" and a long horizontal stroke at the end.

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

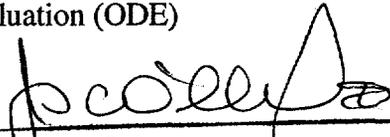
K980475

510(k) Number (if known):

Device Name: **Nidek UniPulse CO2 Laser System**

Indications for Use: Plastic Surgery and Dermatology: UniPulse CO2 Surgical Laser Systems are intended for skin resurfacing for the treatment of wrinkles, rhytids, furrows and acne scar revision.

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division **Sign-Off**)

Division of **General Restorative Devices**

510(k) Number _____

K980475

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use _____