

**SUMMARY OF SAFETY AND EFFECTIVENESS
NIDEK PRIMA KTP SURGICAL LASER SYSTEM**

K973828

REGULATORY AUTHORITY:

JAN - 5 1998

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:

Prima KTP Laser System

DEVICE COMMON NAME:

KTP Surgical Laser System

DEVICE CLASSIFICATION:

KTP 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 Prima KTP Laser System is intended for all cleared Laserscope AURA KTP applications.

COMPARISON WITH PREDICATE DEVICE:

The Nidek KTP system is substantially equivalent to Laserscope's Aura KTP laser system.

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

Since the Nidek Prima KTP 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.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 5 1998

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

Re: K973828
Trade Name: Prima KTP Laser System
Regulatory Class: II
Product Code: GEX
Dated: October 1, 1997
Received: October 7, 1997

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.

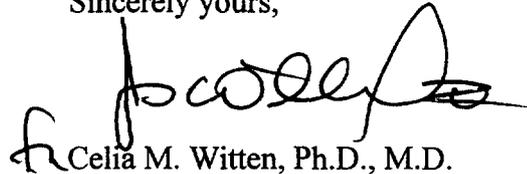
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirements, 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 and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K973828
Device Name: **Nidek Prima KTP Laser System**

Indications for Use: The Prima KTP lasers are intended for the surgical treatment (i.e., incision, excision, ablation, coagulation, vaporization, debulking or hemostasis) of soft tissue in all surgical applications. This includes:

Head and Neck (ENT), General Surgery, Plastic Surgery, Thoracic Surgery and Urology.

Dermatology: Photocoagulation of cutaneous lesions, including the following general categories of lesions: Vascular lesions; Angiomas, hemangiomas, telangiectasia. Benign pigmented lesions; Nevi, Lentigines, chloasma, café-au-lait, Tattoos. Other Cutaneous Lesions, Verrucae, Skin Tags, Keratoses, Plaques. Cutaneous Lesion Treatment Goals Include; Hemostasis, Color Lightening, Blanching, Flattening, Reduction of Lesion Size.

Gastroenterology: Ablation of esophageal neoplastic obstructions, including squamous cell carcinoma and adenocarcinoma. Ablation and excision of obstructive colorectal carcinoma. Hemorrhoidectomy. Ablation of villous adenoma in non-operative patients. Ablation of familial polyposis of the colon. Excision of gastric cancer. Ablation of sessile polyps of the colon.

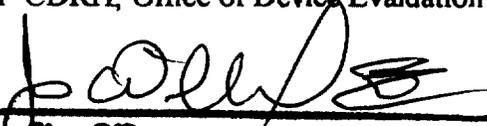
Gynecology: Vaporizing, incising or coagulating tissue associated with treatments for conditions such as; Endometriosis, Cervical, vulvar and vaginal intraepithelial neoplasia. Condyloma acuminata. Interuterine septum. Intrauterine adhesions. Submucosal fibroids.

Neurosurgery: Vaporizing, coagulating, incising, excising, debulking, and ablating neurological tissue in both open and endoscopic intracranial procedures such as: Third ventriculostomy, transseptal fenestration, intraventricular cysts fenestration, ventriculocystostomy, tumor biopsy and excision, removal of proximal shunts occluded by choroid plexus.

Ophthalmology: Post-vitreotomy endophotocoagulation of the retina.

Spinal Surgery: Percutaneous lumbar diskectomy.

Concurrence of CDRH, Office of Device Evaluation (ODE)



(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K973828

Prescription Use X
(Per 21 CFR 801.109)

OR

Over the Counter Use _____