



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Marilyn M. Chou, Ph.D.  
Executive Vice President  
Xintec Corporation  
900 Alice Street  
Oakland, California 94607

JUN 17 1997

Re: K971065  
Trade Name: Dentica Pulsed Nd:YAG Laser System and Accessories  
Regulatory Class: II  
Product Code: GEX  
Dated: March 22, 1997  
Received: March 24, 1997

Dear Dr. Chou:

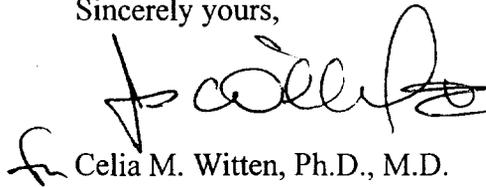
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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", with a stylized flourish 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

**510(k) Premarket Notification #K97-1065**  
**Dentica (tm) Pulsed Nd:YAG Laser System and Accessories**  
**Indications For Use**

The Dentica Pulsed Nd:YAG Laser System and accessories is indicated for incision/excision, ablation, and coagulation (homeostasis) of soft tissue and cartilage. Soft tissue which may be encountered in surgical procedure includes skin, subcutaneous tissue, striated and smooth muscle, cartilage, mucous membrane, lymph vessels and nodes, organs and glands.

Specific surgical specialties include:

Dentistry

Laser Curettage; Gingivectomy; Gingivoplasty; Incision and Excision

Oral Surgery

Frenectomy; Incisional and Excisional Biopsy; Incisional and Excisional aphous ulcers; Incision of infection when used with antibiotic therapy; Excision and ablation of benign and malignant lesions and conditions; Homeostasis; Operculectomy, and Crown lengthening.

Ear Nose & Throat (ENT)

Head and Neck Surgery

Thoracic Surgery

Neurology (homeostasis only)

Dermatology

Plastic Surgery

General Surgery

  
\_\_\_\_\_  
(Division 510(k))  
Division of General Restorative Devices  
510(k) Number                     

K971065

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

