



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

NOV - 3 1997

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

Re: K971912  
Trade Name: Protégé and Protégé LP Er:YAG Laser Systems and Accessories  
Regulatory Class: II  
Product Code: GEX  
Dated: August 1, 1997  
Received: August 5, 1997

Dear Dr. Chou:

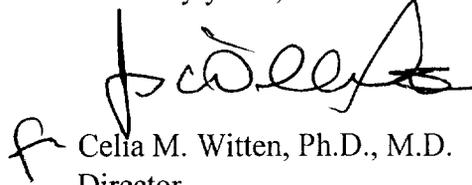
We have reviewed your Section 510(k) notification of intent to market the devices referenced above and we have determined the devices are substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date 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 devices, 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 devices are classified (see above) into either class II (Special Controls) or class III (Premarket Approval), they may be subject to such additional controls. Existing major regulations affecting your devices 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. In addition, FDA may publish further announcements concerning your devices in the Federal Register. Please note: this response to your premarket notification submissions 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 devices as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your devices to a legally marketed predicate device results in a classification for your devices and thus, permits your devices to proceed to the market.

If you desire specific advice for your devices 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 devices, 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 'C. Witten', is written over the typed name. The signature is fluid and cursive.

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: #K971912

Device Name: Protégé (tm) Er:YAG Laser Systems and Accessories

Indications For Use:

The Protégé and Protégé LP Er:YAG Laser Systems and accessories are indicated for incision/excision, ablation, and coagulation (hemostasis) of soft tissue. Soft tissue which may be encountered in surgical procedure includes skin, subcutaneous tissue, striated and smooth muscle, mucous membrane, lymph vessels and nodes, organs and glands and specifically for the following indications. Specific surgical specialties include:

Dentistry

Soft tissue (incision, excision, ablation and coagulation)

Dermatology and Plastic Surgery

Epidermal nevi, telangiectasia, spider veins, actinic cheilitis, keloids, verrucae, skin tags, anal tags, keratoses, scar revision, debulking benign tumors, decubitus ulcers

Oral/Maxillofacial (benign oral tumor, oral and glossal lesions and gingivectomy)

Ear Nose & Throat (ENT), Head and Neck Surgery

GI, GU, GYN and Pulmonary Surgery

Orthopedic Surgery

Thoracic Surgery

Ophthalmology

Podiatry

General Surgery

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

K971912

Prescription Use

OR

Over-The-Counter Use

(21 CFR 801.109)