

K973764

Attachment I  
510(K) Summary  
Temperature Diagnostic Accessory

This 510(K) Summary of safety and effectiveness for the Temperature Diagnostic Accessory is submitted in accordance with the requirements of the SMDA 1990 and following guidance concerning the organization and content of a 510(K) summary.

Applicant: New Star Lasers  
Address: 11802 Kemper Road  
Auburn, CA 95603  
Contact Person: Nina Davis  
Telephone: (916) 823-1434  
(916) 823-1446  
Preparation Date: 10-1-97  
Device Trade Name: Temperature Diagnostic Accessory  
Common Name: Temperature Diagnostic Accessory  
Classification Name: Instrument, Surgical, Powered, laser  
79-GEX  
21 CFR 878-4810

DEC 31 1997

Legally Marketed Predicate Device: Fiber Tipped Protection System accessory cleared for market as part of the Optica 60 Nd: YAG Laser System, Mfg. by Xintec Corp., Oakland, CA Cleared under 510(K) # K912703

Description of the Temperature Diagnostic Accessory The Temperature Diagnostic Accessory is a temperature detector which will provide the laser operator with a control panel read out of the temperature of the treatment area..

Intended use of the Temperature Diagnostic Accessory The Temperature Diagnostic Accessory is intended for use as a sensing device to measure and display the temperature of the treatment area during procedures with the ND-130 Laser.

Nonclinical Performance Data: None  
Clinical Performance Data: None

Conclusion: The Temperature Diagnostic Accessory is substantially equivalent to other existing automatic temperature measuring accessories.

Additional Information: None requested at this time



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

Mr. Dave Hennings, M.S.  
President  
New Star Lasers, Incorporated  
11802 Kemper Road  
Auburn, California 95603

Re: K973764  
Trade Name: Temperature Diagnostic Accessory  
Regulatory Class: II  
Product Code: GEX  
Dated: October 1, 1997  
Received: October 2, 1997

DEC 31 1997

Dear Mr. Hennings:

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.

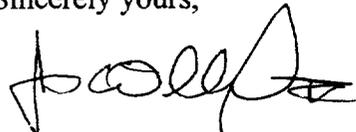
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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,



fr 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

INDICATION FOR USE STATEMENT

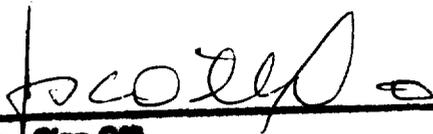
510(k) Number: K973764

Device Name: New Star Temperature Diagnostic Accessory  
Indications for Use:

**The Temperature Diagnostic Accessory is intended for use as a sensing device to measure and display the temperature of the treatment area during procedures with the ND-130 Laser.**

(Please do not write below this line - Continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

  
**(Division Sign-Off)**  
**Division of General Restorative Devices**  
**510(k) Number** K973764

Prescription Use X  
(per 21 CFR 801.109)

OR

Over-the-Counter Use \_\_\_\_\_