

K 962791

### 510(k) Summary

**Submitter:** New Star Lasers, Inc.  
11802 Kemper Road  
Auburn, California 95603  
916-823-1434  
916-823-1446 fax

**Contact:** David R. Hennings  
President

**Date Summary Prepared:** July 16, 1996

**Device Trade Name:** New Star Model 130 6-Watt Nd:YAG Laser System

**Common Name:** Surgical laser system

**Classification Name:** Instrument, surgical, powered, laser  
79-GEX  
21 CFR 878.48

**Equivalent Devices:** Laser:  
New Star Model 600 Holmium Laser System, New Star Lasers, Inc.  
(K952489)

Optica 60 Nd:YAG Laser System, XINTEC Corp.  
(K912703)

Opmilas 144 Nd:YAG Laser System, Carl Zeiss, Inc.  
(K932376, K933322)

ADL 400, Sunrise Technologies, Inc.  
(K920106)

Optional Coolant  
Gebauer Fluoro-Ethyl topical refrigerant  
(Pre-Amendment device)

**Device Description:** The New Star Model 130 laser is a compact, portable, self-contained surgical laser system that produces a variable 1-6 watt beam of infrared radiation at 1320nm wavelength. The system emits a pulsed laser beam which is delivered to the treatment site using a fiber optic delivery system. A visible light 0.5 mW HeNe laser beam at 632.8nm is used for aiming.

The system is comprised of a laser console, a fiber-optic delivery system, a foot switch and a removable electronic key interlock. The system provides safety features that are designed to protect the operator and patient from high voltage and laser emissions.

NSB  
A 200

**510(k) Summary (cont'd)**

**Intended Use:** For use in general surgery for the incision, excision, ablation, vaporization, coagulation of soft tissue.

**Comparison:** Pulse duration, pulse repetition rate, power, energy per pulse, exposure, aiming beam, beam delivery, energy monitor and fiber calibration for the New Star Model 130 6-Watt Nd:YAG Laser System fall within the range of values available on the referenced equivalent systems.

**Nonclinical Performance Data:** none

**Clinical Performance Data:** none

**Conclusion:** The New Star Model 130 6-Watt Nd:YAG Laser System is substantially equivalent to other existing surgical laser systems in commercial distribution for the incision, excision, ablation, vaporization and coagulation of soft tissue.

**Additional Information:** None requested at this time.

hsh

510(k) PREMARKET NOTIFICATION  
New Star Model 130 6-watt Nd:YAG Laser System  
New Star Lasers, Inc.  
July 16, 1996

---

Page 1 of 1

510(k) Number (if known): *not assigned yet K 962791*

Device Name: New Star Model 130 6-watt Nd:YAG Laser System

Indications for Use: For use in dermatology for incision, excision, ablation and vaporization with hemostatis of soft tissue.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

-----  
Concurrence of CDRH, Office of Device Evaluation (ODE)

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

OR

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

(Optional Format 1-2-96)

*NS*  
*11*