

510(k) Summary

**Kaplan PenduLaser 115 CO₂ Surgical Laser
with OptoScan II Scanner Accessory**

Common/Classification Name: Laser Surgery Device, 21 CFR 878.4810
Optomedic Medical Technologies
Yoni Netanyahu 3-B
Or-Yehuda 60376
ISRAEL

Contact: Alex Harel, Prepared: January 29, 1998

A. LEGALLY MARKETED PREDICATE DEVICES

The Kaplan PenduLaser 115 CO₂ Surgical Laser with OptoScan II Scanner Accessory is substantially equivalent to the Coherent UltraPulse 5000 system cleared under K963339 and to the Sharplan SilkTouch/Sharplan 1020 Laser cleared under K860087, K960521, and K961935. The new device is actually a combination of two products already cleared under K950313 (the laser) and K964684 (the scanner), and so the new device can also be considered to be substantially equivalent in parts to these two devices.

B. DEVICE DESCRIPTION

The Kaplan PenduLaser 115 CO₂ Surgical Laser with OptoScan II Scanner Accessory consists of the laser, the Scanner Controller Box, a Footswitch Adapter box, the Sahar SofTouch Scanner, and the handpiece. The Controller houses the electronics and power supply and interfaces to the Pendulaser for communication through the Footswitch Adaptor Box.

C. INTENDED USE

The Kaplan PenduLaser 115 Surgical Laser with OptoScan II Scanner accessory is indicated for surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: Dermatology, Plastic Surgery, Podiatry, Neurosurgery, Gynecology, Otorhinolaryngology, Arthroscopy (knee), Open & Endoscopic General Surgery.

The Kaplan PenduLaser 115 Surgical Laser with OptoScan II Scanner accessory is safe and effective when indicated for use in specific surgical applications including:

- Ablation, vaporization, excision, incision, and coagulation of soft tissue in dermatology and plastic surgery in the performance of laser skin resurfacing, laser derm-abrasion, and laser burn debridement.
- Laser skin resurfacing (ablation and/or vaporization) in dermatology and plastic surgery for the treatment of wrinkles, rhytids, and furrows.
- Laser skin resurfacing (ablation and/or vaporization) of soft tissue in dermatology and plastic surgery for the reduction, removal, and/or treatment of actinic keratosis, solar/actinic elastosis, actinic cheilitis, lentinges, uneven pigmentation/dyschromia, acne scars, surgical scars, keloids, hemangiomas (including buccal hemangiomas), tattoos, telangiectasia, squamous cell carcinoma, epidermal nevi, xanthelasma palpebrarum, syringoma, and verrucae vulgares (warts).
- Laser incision and/or excision of soft tissue in dermatology, plastic and general surgery for the performance of blepharoplasty.

D. SUBSTANTIAL EQUIVALENCE SUMMARY

The **KAPLAN PenduLaser 115 Surgical Laser with OptoScan II Scanner Accessory** is a medical device, and it has the same indications for use and target population as the legally marketed predicate devices.

The **KAPLAN PenduLaser 115 Surgical Laser with OptoScan II Scanner Accessory** has the same technological characteristics as the predicate devices and these characteristics are sufficiently precise to ensure equivalence. This premarket notification has described the characteristics of the **KAPLAN PenduLaser 115 Surgical Laser with OptoScan II Scanner Accessory** in sufficient detail to assure substantial equivalence.

E. TECHNOLOGICAL CHARACTERISTICS

The technological characteristics of the combined new device are unchanged from those of the component devices and are the same as those of the predicate devices.

F. CONCLUSIONS

This pre-market submission has demonstrated Substantial Equivalence, as defined and understood in the Federal Food Drug and Cosmetic Act and various guidance documents issued by the Center for Devices and Radiological Health, to the predicate devices.

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SEP 22 1998

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Optomedic Medical Technologies Limited
c/o Whit Athey, Ph.D.
C.L. McIntosh & Associates
12300 Twinbrook Parkway, Suite 625
Rockville, Maryland 20852

Re: K980398

Trade Name: Kaplan PenduLaser 115 CO₂ Surgical Laser with OptoScan II
Regulatory Class: II
Product Code: GEX
Dated: August 20, 1998
Received: August 20, 1998

Dear Dr. Athey:

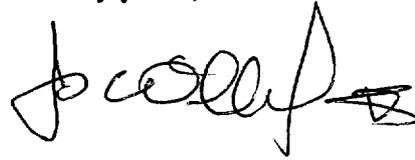
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 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/dsma/dsmamain.html>".

Sincerely yours,



fm 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

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): K980398

Device Name: Kaplan PenduLaser 115 Surgical Laser with OptoScan II Scanner

Indications For Use:

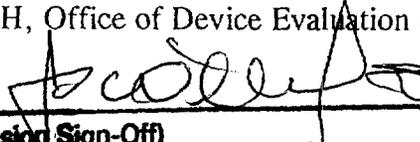
The Kaplan PenduLaser 115 Surgical Laser with OptoScan II Scanner accessory is indicated for surgical applications requiring the ablation, vaporization, excision, incision, and coagulation of soft tissue in medical specialties including: Dermatology, Plastic Surgery, Podiatry, Neurosurgery, Gynecology, Otorhinolaryngology, Arthroscopy (knee), Open & Endoscopic General Surgery.

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Concurrence of CDRH, Office of Device Evaluation (ODE)


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K980398

Prescription Use OR Over-The-Counter Use
(Per 21 CFR 801.109)

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