

CLINICON CORPORATION

Premarket Notification [510(k)] -- K983463
Diamond LaserKnife™

K9P 3463

DEC 11 1998

FDA Premarket Notification [510(k)] Summary

Preparation Date: 24 November 1998

Contact: Gerald S. Palecki, Director, Quality and Regulatory

Device Name: Proprietary: Diamond LaserKnife™

Common: Laser Scalpel

Predicate Device: Sapphire Laser Scalpel, reference K863086

Device Description:

The Diamond LaserKnife™ is an accessory hand piece for CO₂ laser systems, that consists of a diamond cutting blade and handle coupled to a flexible fiber guide cable that conducts CO₂ laser energy to the blade tip. The laser energy is emitted from the facets at the blade tip to the tissue when the laser is energized.

Intended Use:

The Diamond LaserKnife™ is indicated for incision and/or excision, with or without cauterization/coagulation, of soft tissue in open dental, dermatology, general and plastic surgery, neurosurgery, ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, and urological procedures. Refer to the laser system Directions for Use manual for specific indications for Use.

Technological Characteristics Compared to Predicate Device:

A crystal with sharpened edges is used as a scalpel to cut tissue during surgical procedures and also conducts laser energy to the tissue to cauterize and coagulate.

Non-Clinical Tests:

The Diamond LaserKnife™ performance characteristics have been evaluated through analysis of laser energy fields emitted from the tip when the laser is energized compared to similar devices cleared for marketing in the past.

Conclusions Drawn from Tests and Analysis:

The predicted energy levels at the point of application meet criteria derived from performance of similar devices, based upon fluence (energy per unit area) and reaction of tissue to the discrete values of fluence.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 11 1998

Mr. Gerald S. Palecki
Director, Quality and Regulatory
Clinicon Corporation
2752 Loker Avenue West
Carlsbad, California 92008

Re: K983463
Trade Name: Diamond LaserKnife™
Regulatory Class: II
Product Code: GEX
Dated: September 30, 1998
Received: October 1, 1998

Dear Mr. Palecki:

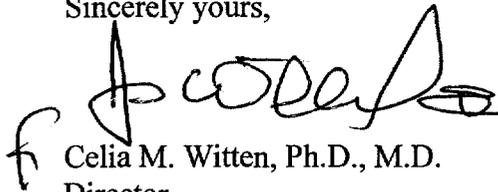
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 requirement, 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,

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) Number: K983463

Device Name: Diamond Laserknife™

Indications for Use:

The Diamond LaserKnife™ is indicated for incision and/or excision, with or without cauterization/coagulation, of soft tissue in open dental, dermatology, general and plastic surgery, neurosurgery, ophthalmology, oral surgery, oto-rhino-laryngology, podiatry, and urological procedures.

See Attachment 2 for a listing of medical specialties and typical contact laser procedures.

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(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 K983463

(Optional Format 3-10-98)

Prescription Use X
(Per 21 CFR 801.109)

CLINICON CORPORATION

Premarket Notification [510(k)] -- K983463
Diamond LaserKnife™Attachment 2

Listing of medical specialties and typical contact laser procedures.

1. Dentistry/Oral Surgery

Incisional/excisional biopsies, removal of benign and cancerous lesions, frenectomy, gingivectomy, gingivoplasty, operculectomy, coagulation of graft donor sites, removal of vascular lesions, minor flap surgery, leukoplakia, and lymphangioma.

2. Dermatology

Removal of warts, neurofibromas, hemangioma, epidermal nevi, eruptive vellus hair cysts, telangiectasia, basal cell carcinoma, and granuloma.

3. General and Plastic Surgery

Removal of skin tumors, hemorrhoidectomy, lipomas, partial splenectomy, and rectal strictures. Blepharoplasty, breast reduction/reconstruction, and hair grafts.

4. Neurosurgery:

Incision/excision of tumors, lesions, and cysts.

5. Ophthalmology

Incision/excision of periorbital lesions.

6. Oto-rhino-laryngology

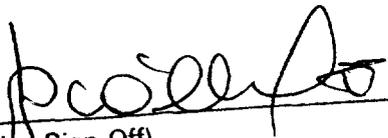
Excision of pulmonary lesions, vocal cord dysplasia and carcinoma, bronchoectomy, cordectomy, polyps, larynx leukoplakia, papillomas, lymphangioma, and myringotomy.

7. Podiatry

Excision of Morton's neuroma, porokeratotic lesions, and plantar warts.

8. Urology

Benign neoplasia and carcinoma of external genitalia, urethral condyloma, phimosis, and renal resection.

Prescription Use _____
(Per 21 CFR 801.109)

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

K983463