

NOV 25 1998

K9P3020

APPENDIX E

510(k) SUMMARY
COSMOS MEDICAL TECHNOLOGY
COMPACT KTP LASER

This 510(k) summary of safety and effectiveness for the COSMOS Medical Technology COMPACT KTP laser is submitted in accordance with the requirements of SMDA 1990 and follows Office of Device Evaluation guidance concerning the organization and content of a 510(k) summary.

Applicant: COSMOS Medical Technology

Address: P.O. Box 27210
San Diego, CA 92198

Manufacturer: Crystal Focus, S.A.
19 Rue Ampere, BP 35
91302 Massy, France

(011) +33-1 6920 8454
(011) +33 1 6981 7639 (Fax)

Preparation Date: August 1998
(of the Summary)

Device Name: COMPACT KTP laser

Common Name: Frequency doubled Nd:YAG laser

Classification Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
21 CFR 878.4840).
Product Code: GEX.
Panel: 79

Legally marketed predicate device: Laserscope Aura Laser System; American Laser Medical NovuLase 660 Laser System; and Laserscope KTP/532 and KTY/YAG lasers.

Device description: The COSMOS Medical Technology COMPACT KTP laser emits a beam of coherent light at 532 nanometers as do the predicate devices.

Indications for use: The COSMOS Medical Technology COMPACT KTP laser is intended for the coagulation, ablation, vaporization, incision, vaporization, incision, excision, or cutting of soft tissue in dermatology.

Comparisons: The specifications of and indications for the ~~COSMOS Medical Technology COMPACT KTP laser~~ are the same as or very similar to those of the claimed predicates.

Performance Data: None. ~~The specifications and indications for use of the COSMOS Medical Technology COMPACT KTP laser~~ are the same or very similar to those of the claimed predicate devices.

Because of this, performance data were not required.

CONCLUSION: ~~Based on the similarities of specifications and indications for use,~~ COSMOS Medical Technology believes that the COMPACT KTP laser described in this notification is substantially equivalent to the cited legally marketed predicate devices.



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Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. John P. Clark
President
COSMOS Medical Technology
P.O. Box 27210
San Diego, California 92198

Re: K983020
Trade Name: COMPACT KTP Laser
Regulatory Class: II
Product Code: GEX
Dated: August 27, 1998
Received: August 31, 1998

Dear Mr. Clark:

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.

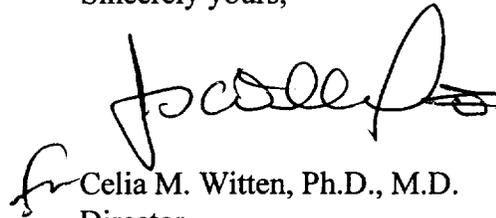
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially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

Page 2 - Mr. John P. Clark

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,

A handwritten signature in black ink, appearing to read "Celia M. Witten". The signature is written in a cursive style with a large, looping initial "C".

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

INDICATIONS FOR USE STATEMENT

510(K) Number (if known): K983020

Device Name: COSMOS Medical Technology COMPACT KTP Laser

Indications For Use Statement:

~~The COMPACT-KTP laser is intended for the coagulation, ablation, vaporization, incision, excision, and/or cutting of soft tissue in dermatology.~~

~~Examples of applications include:~~

- ~~Benign Vascular Lesions~~
- ~~Port Wine Stains~~
- ~~Erythrosis~~
- ~~Couperosis~~
- ~~Facial Telangiectasias~~
- ~~Leg Veins - Micro-varicosities~~
- ~~Benign Pigmented Lesions~~
- ~~Senile Lentigo~~

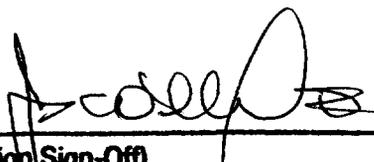
~~The examples are not intended to be exhaustive or complete but to serve as a general guide to surgeons.~~

~~Labeling in the draft manual restricts the COMPACT KTP laser to prescription use (see page 13 of the draft manual - APPENDIX A).~~

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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


 (Division Sign-Off)
 Division of General Restorative Devices
 510(k) Number K983020