Xanova
CORPORATION

K971539

JUN - 3 1997

9.0 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990.

1. Submitter's name, address, telephone, and contact person:

Xanova Corporation
15018 N.E. 177th Drive
Woodinville, WA 98072
206/481-6223
Michael Levy, President

2. Date summary prepared: April 11, 1997

3. Product trade or proprietary name: Novatip NT family of laser handpiece tips

4. Product common name: Laser Handpiece Tips

5. Product classification name:

21CFR § 878.4810 Lasers in general and plastic surgery and in dermatology
21CFR § 874.4500 Lasers for use in ENT
21CFR § 884.4550 Gynecologic surgical laser

6. Legally marketed predicate devices used for equivalency:

Luxar laser handpiece tips models LXT-C5, LXT-C10, LXT-005TSS, LXT-120ST, LXNS-T3, as cleared under K960475 Luxar Modified CO_2 Surgical Laser System

7. Description: The Xanova Novatips constitute the disposable end element of the hollow fiber delivery system of a CO_2 surgical laser.

8. Statement of intended use: The intended use of the Xanova tips is identical to that of the Luxar tips, namely to constitute the disposable end element of the delivery system of the Luxar laser used for the vaporization, ablation, incision, excision, or photocoagulation of soft tissue in the surgical specialties of gynecology, dermatology, dentistry and oral surgery, general surgery, otorhinolaryngology, and podiatry. No new indications were sought in the premarket notification and no clinical data were presented.

9. Technological characteristics:

The Xanova tips function in the same manner, and according to the same optical principles as the predicate Luxar tips. The Xanova tips operate within the same range of spot size, power, and power density as the Luxar tips, and have similar transmission efficiencies. The output beam of the Xanova tips has the same mode structure as the output beam of the Luxar tips, and the effect on tissue is the same. The Xanova tips are constructed of materials that are also found in the Luxar tips, although these materials are incorporated in different ways in some cases. The Xanova tips however, do not use toxic lead fluoride, as do the Luxar tips. Xanova believes that the minor differences in performance and differences in construction techniques (where they exist) do not raise any new issues of safety and effectiveness.

Advisory: *This information was prepared for the sole purpose of compliance with the Safe Medical Devices Act of 1990. It does not imply that the procedures described herein can be performed with the equipment described without substantial risk of personal injury or death to patients or operators due to operator error or in high-risk procedures.*

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN - 3 1997

Mr. Michael Levy
President
Xanova Corporation
15018 N.E. 177th Drive
Woodinville, Washington 98072

Re: K971539
Trade Name: Novatip Family of Laser Handpiece Tips
Regulatory Class: II
Product Code: GEX
Dated: April 11, 1997
Received: April 28, 1997

Dear Mr. Levy:

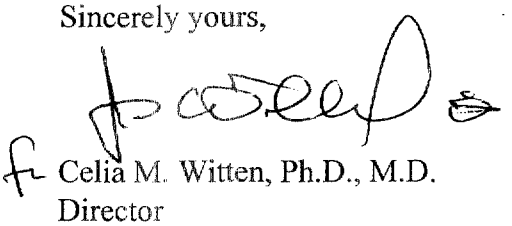
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of 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 (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 Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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,



for 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

K971539

5.2 Intended Use and Indications for Use

The intended use of the Xanova tips is to comprise the distal end element of a surgical CO_2 laser beam delivery system for the incision, excision, ablation, or photocoagulation of soft tissue.

Representative examples of indications for use in various specialties are listed below.

Gynecology—excision and vaporization of cervical, vulvar, and perineal condyloma; ablation of vaginal and vulvar intraepithelial neoplasia; herpes vaporization; vaporization of urethral caruncle; I&D Bartholin's and nubothian cysts.

Dermatology—port wine hemangioma removal; rhinophyma reduction; telangiectasia removal; wart removal; basal squamous cell carcinoma removal; blepharoplasty; xanthalasma removal; removal of neurofibromas, hemangiomas, nevi, and tricoeptiheliomas; dermabrasion for lentigos, keratoses, actinic keratosis and actinic chleilitis.

Dentistry/Oral Surgery—gingivectomy; frenum release; gingivoplasty; removal of soft tissue, cysts, and tumors.

General Surgery—hemorrhoid removal; skin tag vaporization; pilodidal cyst removal and repair; debridement of decubitus ulcers and stasis ulcers; mastectomy; breast biopsy; reduction mammoplasty; cytoreduction for metastatic disease; many dermatological procedures.

Otorhinolaryngology— lymphangioma removal; turbinectomy.

Podiatry—plantar wart vaporization; fungal nail treatment; partial and complete matrixectomy; porokeratoma ablation; Morton's neuroma removal; ingrown toenail treatment.

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K971539

Prescription Use ✓
(Per 21 CFR 801.109)