K032271 1/1

SEP 1 0 2003

510(k) Summary

1. Submitter's Name, Address and Contact Person

Submitter
Wartner USA b.v.
World Trade Center
Beursplein 37 (Room 405)
The Netherlands

Telephone: +31 10 405 6406
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Contact Person
Nancy Lum-Wilson
N. Wilson Consulting Inc.
65 Ava Crescent
Richmond Hill, Ontario
CANADA L4B 2X5

Telephone: 905-884-7855
Facsimile: 905-508-8599

Date Summary Prepared: June 30, 2003

2. Name of Device

WARTNER® Wart Removal System (for OTC use)

3. Name of Predicate Device(s)

- Wartner® Wart Removal System for OTC use, by Wartner Medical Products **(Primary Predicate)**

- Histofreezer® Portable Cryosurgical System, by Orasure Technologies Inc. **(Labeling predicate)** K022461
- Tinamed® Plantar Patch, by Stiefel laboratories, Inc. **(Labeling predicate)**
- DuoFilm® Salicylic Acid Wart Remover indicated for common warts and plantar warts, by Schering-Plough HealthCare Products, Inc. **(Labeling predicate)**
- Clear Away® System Plantar Wart Remover for Feet, by Schering-Plough HealthCare Products, Inc. **(Labeling predicate)**
- Wartner Pro®, by Wartner Medical Products **(Labeling predicate)**

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 1 0 2003

Wartner USA b.v.
c/o Ms. Nancy Lum-Wilson
N. Wilson Consulting, Inc.
65 Ava Crescent
Richmond Hill, Ontario
Canada L4B 2X5

Re: K032271
Trade/Device Name: WARTNER® Wart Removal System
Regulation Number: 21 CFR 878.4350
Regulation Name: Cryosurgical unit and accessories
Regulatory Class: II
Product Code: GEH
Dated: July 18, 2003
Received: July 23, 2003

Dear Ms. Lum-Wilson:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer 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,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number: K032271

Device Name: **WARTNER® Wart Removal System**

Indications for Use: **WARTNER® Wart Removal System is indicated for the over-the-counter treatment of common warts and plantar warts.**

Miriam C Provost

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K032271

(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) (Optional Format 1-2-96)