510(k) SUMMARY

K973174

OCT 30 1997

Trade name: Sonique™ Hair Remover

Marketed by: Global TV Concepts Ltd.
776 South Military Trail
Deerfield Beach, Florida 33442
(954) 570-9998; fax (954) 570-9990
Contact: Ms. Laurie Braden

Date prepared: August 22, 1997

Common name: Sonic hair remover

Classification name: Tweezer-type epilator (per 21 C.F.R. § 878.5360)

Intended use: Hair removal

Description: The device works by emitting from the tweezer tips radio frequency energy that is transmitted down an individual hair grasped by the tweezers to the root and papilla of the hair. The tweezers may also be used to slide the hair out after treatment. The radio frequency energy destroys the papilla, with the result that the hair does not grow back. More than one treatment may be necessary.

Substantial equivalence: The device is substantially equivalent to the IGIÁ Hair Removal System, another tweezer-type epilator. Both devices emit a 27 MHz radio frequency signal, with a peak reading of dBμV 107.15 for the Sonique™ and dBμV 105.6 for the IGIÁ. The principal difference between the products is that the Sonique™ Hair Remover relies on 4 "AAA" batteries for its operation, whereas the IGIÁ Hair Removal System uses household electrical energy. Also the Sonique™ uses 6V of electricity to generate the radio frequency signal, whereas the IGIÁ uses 9V.

The safety and efficacy of tweezer-type epilators are discussed in the attached Federal Register notice published by the Food and Drug Administration (FDA) on June 11, 1997, 62 Fed. Reg. 31771-775.

Attachment

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Global TV Concepts, Ltd.
c/o Ms. Samia N. Rodriguez
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, NW, Suite 1200
Washington, District of Columbia 20005

OCT 30 1997

Re: K973174
Trade Name: Sonique™ Hair Remover
Regulatory Class: III
Product Code: KCX
Dated: August 22, 1997
Received: August 25, 1997

Dear Ms. Rodriguez:

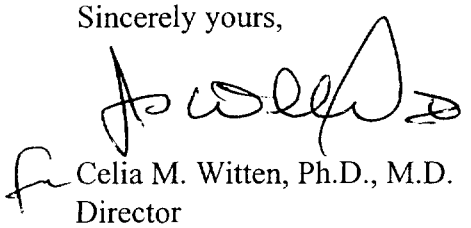
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

Sincerely yours,



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 (if known): K973174

Device Name: Sonique Hair Remover

Indications For Use:

For the removal of hair

(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 K973174

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

(Optional Format 1-2-96)