



K972695

510(k) SUMMARY

FINALLY FREE ULTRA

Finally Free Ultra is a tweezer-type epilator for the removal of unwanted body and facial hair. It is designed for consumer home use. Reviewed by the General and Plastic Surgery Device Classification Panel, tweezer-type epilators are assigned the Product Code KCX and are regulated under 21 CFR 878.5360. Tweezer-type epilators are Class III devices, although FDA has proposed reclassifying them into Class I.

The device removes hair by the application of radio frequency energy to the hair shaft, which in turn conducts it to the hair root. There the energy causes the root to separate from follicle, thereby causing the hair to fall out. Further damage to the surrounding tissue stunts hair growth. This patented process is called NU-Trolysis.

Finally Free Ultra is substantially equivalent to Forever Free, another consumer-use tweezer-type epilator manufactured by Burke/Neutech (K952117). Both are plastic encased units which plug into a standard 110V wall socket and which convert the AC current into radio frequency energy by means of a crystal oscillating component and both amplifying and filtering circuitry. The energy is delivered by a line cord attached to a hand-held wand with a tweezer which grasps the individual hair.

Energy outputs for the two devices were measured as follows:

	FINALLY FREE (6 Units)	FOREVER FREE (2 Units)
Frequency (MHZ)	27.100 - 27.322	27.064 - 27.112
Voltage (p-p)	39.2 - 59.4	30.1 - 31.2

The two devices differ slightly in that much of Finally Free's essential electronic components are contained within the base unit whereas for Forever Free most components are found within the wand. Also, a power select knob is provided with Finally Free, but not for Forever Free.

Thomas Blake 7/16/97
 Thomas Blake, R.Ph. Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20856

Thomas Blake, R. Ph.
MEHL/Group Marketing
48 Mt. Olive Road
Budd Lake, New Jersey 07828

OCT 22 1997

Re: K972695
Trade Name: Finally Free *ULTRA*
Regulatory Class: III
Product Code: KCX
Dated: July 17, 1997
Received: July 18, 1997

Dear Dr. Blake:

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,


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

510(k) Number (if known): K972695

Device Name: FINALLY FREE ULTRA

Indications for Use:

The FINALLY FREE Ultra tweezer-type epilator is indicated for the removal of unwanted body and facial hair. Like the predicate devices, it is specifically designed for use by consumers.

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

Concurrence of CDRH, Office of Device Evaluation (ODE) _____

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(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K972695

Prescription Use X
(Per 21 CFR 801.109)

OR Over-The-Counter Use X

(Optional Format 1-2-96)