

JUN 29 1998

**MEHL / Biophile International
CORPORATION**

K980753

4127 N.W. 27th Lane, Suite A
Gainesville, Florida 32606
Phone (352) 373-2565
Fax (352) 373-2481

510(k) SUMMARY

CHROMOSCAN SCANNER

for the

**CHROMOS 694 RUBY LASER
FOR HAIR REMOVAL**

The ChromoScan is a scanner which is used with the Chromos 694 Ruby Laser for the removal of unwanted body and facial hair. Lasers for such dermatological use were reviewed by the General and Plastic Device Classification Panel and are assigned the Product Code 79 GEX. They are regulated under 21 CFR 878.4810 as Class II devices.

The hand held ChromoScan attachment enables treatment of multiple, rather than single hairs, thereby increasing efficiency and adding to the safety of the parent laser. The unit lays down a mathematically precise treatment grid whereby overlap is reduced and thermal recovery time is optimized. It is expected to lessen potential operator error by diminishing the time and tedium associated with one-hair-at-a-time hair removal procedures. Moreover, safeguards within the Chromos 694's intrinsic software insure that the scanner's fluences do not exceed those of the basic laser, i.e., no more than 20J/cm².

ChromoScan is substantially equivalent to the other laser delivery attachment, the fiber optic handpiece. Both produce the same spot size, 7mm, and energies, as shown by computer-generated thermographic profiles. Reliability of the scanner is assured by state-of-the-art validation procedures and final system inspections.

Preliminary use of the ChromoScan on subjects in Europe produced no concerns about safety.


Thomas Blake, R.Ph.
Regulatory Strategist

5/13/98
Date



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 29 1998

Thomas Blake, R.Ph.
MEHL/Biophile International Corporation
48 Mt. Olive Road
Budd Lake, New Jersey 07828

Re: K980753
Trade Name: Chromoscan Scanner
Regulatory Class: II
Product Code: GEX
Dated: May 27, 1998
Received: May 28, 1998

Dear Mr. Blake:

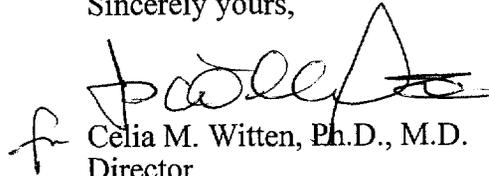
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of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

A handwritten signature in black ink, appearing to read 'Celia M. Witten', with a large, stylized initial 'C' and a horizontal line extending to the right.

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): K980753

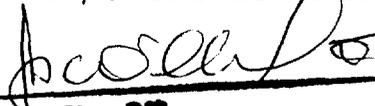
Device Name: CHROMO SCAN SCANNER

Indications for Use:

To be used with the MEHL Chromos 694 Ruby Laser for the removal of unwanted body and facial 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** K980753
510(k) Number _____

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____
(Optional Format 1-2-96)