

K971814

**MEHL / *Biophile International***  
**CORPORATION**

AUG - 1 1997

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

**510(k) SUMMARY**

**CHROMOS 694 RUBY LASER  
FOR HAIR REMOVAL**

The Mark I Chromos 694 Ruby Laser is a laser instrument used in medical practice for the removal of unwanted body and facial hair. Reviewed by the General and Plastic Surgery Device Classification Panel, medical lasers are assigned the Product Code 79GEX and are regulated under 21 CFR 878.4810 as Class II (Performance Standards) devices.

The Mark I Chromos 694 Ruby Laser is substantially equivalent to its predecessor, the MEHL Ruby Laser for Hair Removal. Both use the same wavelength, deliver the same energies to the skin, and are constructed of similar components for the removal of unwanted body and facial hair.

The MEHL Ruby Laser utilized manual controls and a standard, mirrored articulated arm for transmitting laser light to the skin site. Further, it contained a Q-switched feature which was intended for other purposes.

Safety and reliability are improved with the newer version, the Mark I Chromos 694 Ruby Laser. Those improvements include:

- Elimination of the Q-switched option
- Replacement of the articulated arm with optical fiber which eliminates the Gaussian hot spot common to the former
- A 7mm vs. 5mm spot size
- Software directed controls and safeguards which include shutdown provisions for no fewer than seven fault conditions

Establishing substantial equivalence between the two devices were (1) engineering data showing similarity in light delivery characteristics; (2) calculations proving essentially equivalent fluences for the 5mm and 7mm spots; and (3) thermographic profiles, optical fiber vs. articulated arm. Reliability of the newer laser also was assured with a preponderance of quality control and validation information.

**510(k) Summary**

Chromos 694 Ruby Laser for Hair Removal

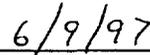
Page 2

In clinical studies with the MEHL Ruby Laser, no unexpected safety issues were identified. No scarring or purpuric reactions were observed. Though hyper- and hypopigmentation were seen infrequently, these effects resolved predictably within a few months.

With the similarity in technical characteristics between the MEHL Ruby Laser and the Chromos 694 Ruby Laser, equivalence in clinical performance can therefore be assured, with more safeguards, better control and increased reliability intrinsic to the newer model.



Thomas Blake, R.Ph.  
Regulatory Strategist



Date



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

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

AUG - 1 1997

Re: K971814  
Trade Name: Chromos 694 (MEHL) Ruby Laser, Model Mark I  
Regulatory Class: II  
Product Code: GEX  
Dated: May 14, 1997  
Received: May 15, 1997

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 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

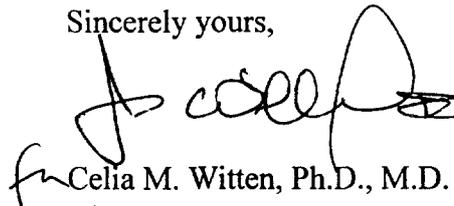
Page 2 - Mr. Thomas Blake, R.Ph.

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 stylized flourish at the end.

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

K9771814/A

510(k) Number (if known): K971814

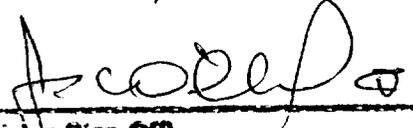
Device Name: CHROMOS 694 (MEHL) RUBY LASER, MODEL MARK I

Indications for Use:

The Chromos 694 (MEHL) Ruby Laser, Mark I, is indicated 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  
510(k) Number K971814

Prescription Use  (Per 21 CFR 801.109)

OR Over-The-Counter Use

(Optional Format 1-2-96)

SK-37