K010311

JUN 2 9 2001

510 (k) Summary
[as required by 21 CFR 807.92]

Date Prepared [21 CFR 807.92(a)(1)]

January 30, 2001

Submitter's Information [21 CFR 807.92(a)(1)]

Euromi
C/o Joseph Azary
Azary Technologies LLC
P.O. Box 2156
Huntington, CT. 06484

Trade Name, Common Name, Classification [21 CFR 807.92(a)(2)]

The device trade names are:

- Lipomatic
- Lipomatic liposuction device

Predicate Device [21 CFR 807.92(a)(3)]

The predicate device is the MicroAire Power Aspiration Device PAD System, which received clearance on 12/10/98 under 510k number K981922 and the Bryon Medical Accelerator Reciprocating Cannula, which received clearance on 8/4/00 under 510k number K001803.

Description of the Device [21 CFR 807.92(a)(4)]

The subject device consists of:

- Lipomatic Control Unit
- Tubing
- Key for the Lipomatic Control Unit
- Oil
- Silicone Pipe
- Lipomatic Cannulas
- Handle with a pneumatic motor
- Collection Container
- Pedal

The handpiece is a motorized pneumatic handle with interchangeable cannulas. The motor is linear and not rotary. Detailed description of the device can be found in the attached instruction manual. The subject device uses external air sources. Therefore, the user chooses the air source and filtration system from readily available sources within a hospital or clinical environment. The Lipomatic does not include an aspirator or compressor.

The subject device includes either stainless steel or Teflon coated cannulas (based on customer order) that vary in length between 150mm-350mm and vary in diameter between 2.5mm-4.5mm.

The subject device has a built in safety feature which stops the device in the event hard tissue is encountered.

Intended Use [21 CFR 807.92(a)(5)]

The subject device is intended to be used for the removal of soft tissue and fluid from the body during general surgical procedures including suction lipoplasty for aesthetic body contouring.

Technological Characteristics [21 CFR 807.92(a)(6)]

The subject device is equivalent to the predicate device, Microaire PAD system, based on the indications for use and similar technological characteristics. The subject device requires less force and has built-in safety features to alert the user that hard tissue has been encountered.

Performance Data [21 CFR 807.92(b)(1)]

The subject device has been used internationally for several years with positive results. A clinical study by Dr. Angelo Rebelo documented the use of the Lipomatic for more than 1600 liposuction/liposculpture procedures with a high success rate and no adverse events.

The components that make contact with the patient are composed of materials that meet biocompatibility requirements as found in ISO 10993.

The subject device has a built in security feature which stops the device when hard tissue is encountered.

The subject device is compliant to European Medical Device Directives and is manufactured by an ISO 9000 certified facilities.

Conclusion [21 CFR 807.92(b)(3)]

The subject device has identical indications for use and similar technological characteristics as the predicate device. The subject device is composed of materials that have passed biocompatibility testing and can be sterilized using commonly accepted methods. Lastly, clinical usage has found the subject device to produce satisfactory results and function safely as a medical device.

We conclude that the subject device is as safe and effective as the predicate device.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 2 9 2001

Euromi S.A.
c/o Mr. Joseph M. Azary
Azary Technologies, LLC
P.O. Box 2156
Huntington, Connecticut 06484

Re: K010311
Trade/Device Name: Euromi S.A. Lipomatic Liposuction Device
Regulation Number: 878.5040
Regulatory Class: II
Product Code: MUU
Dated: May 4, 2001
Received: May 9, 2001

Dear Mr. Azary:

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 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). 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) 594-4659. 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" (21CFR 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/dsma/dsmamain.html".

Sincerely yours,

for Mark N Melkerson

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

5 10(k) Number (if known): K010311

Device Name: Euromi S.A. Lipomatic liposuction device

Indications For Use:

The subject device is intended to be used for the removal of soft tissue and fluid from the body during general surgical procedures including suction lipoplasty for aesthetic body contouring.

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

Concurrence of CDRH Office of Device Evaluation (ODE)

Prescription Use X
(Per 21 CFR 801.109)

OR

Over-The-Counter Use _____

for Mark N Milkerson
(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K010311

(Optional Format 1-2-96)