K091800

MEDICEPT
Unique Concepts in *Medical Instruments*

SEP 23 2009

Attachment III

8.0 Executive Summary

Curve Medical is requesting marketing clearance for a cannula.

Trade Name:	LipoEze Laser Assisted Aspiration Cannula
Device Name:	LipoEze Laser Assisted Aspiration Cannula
Common Name:	Handpiece Accessory
Classification:	Class II
Manufacturer/Sponsor:	Curve Medical, Inc. 2621 Newton Ave South Minneapolis, MN 55405 Registration: (awaiting number)
Consultant/Contact:	MEDIcept. Inc. 200 Homer Ave Ashland, MA 01721
Primary Contact:	F. David Rothkopf 508-231-8842 x20 508-231-8861 Fax
Product Codes:	GEX, Powered Laser Surgical Instrument
Device Classification:	878.4810, Powered Laser Surgical Instrument
Classification Panel:	General & Plastic Surgery

Predicates:

K933017, Sunrise Technologies Model 5030 Suction Handpiece System
878.4810, GEX, Powered Laser Surgical Instrument, Class II

K073617 Osyris: PHARAON LIPO
878.4810, GEX, Powered Laser Surgical Instrument, Class II

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
10903 New Hampshire Avenue
Document Mail Center - WO66-G609
Silver Spring, MD 20993-0002

SEP 23 2009

Curve Medical
% MEDIcept
Mr. F. David Rothkopf
President
200 Homer Avenue
Ashland, Massachusetts 01721

Re: K091800
Trade/Device Name: LipoEze Cannula
Regulation Number: 21 CFR 878.4810
Regulation Name: Laser surgical instrument for use in general and plastic surgery and in dermatology
Regulatory Class: Class II
Product Code: GEX
Dated: September 16, 2009
Received: September 18, 2009

Dear Mr. Rothkopf:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21

CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/cdrh/mdr/ for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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Attachment II

Indications for Use

510(k) Number (if known): K091800

Device Name: LipoEze Cannula

Indications for Use: The LipoEze Cannula is a suction hand piece intended for use with a 980nm laser fiberoptic delivery system during laser assisted lipolysis.

Prescription Use X 21CFR 801, Subpart D **OR** Over-the-Counter Use __ 21CFR 801.109

(PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark P Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091800