K100754

JUN - 9 2010

510(k) SUMMARY

FIBRIJET® GRAFT DELIVERY SYSTEM

SUBMITTED BY: Micromedics, Inc.
1270 Eagan Industrial Road
St.Paul, MN 55121-1385

CONTACT PERSON: Tom Lopac, Manager of Quality & Regulatory Affairs
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TELEPHONE: 651-452-1977

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DATE PREPARED: March 15, 2010

TRADE NAME: FibriJet® Graft Delivery System

COMMON NAME: Piston Syringe

PRO CODE: FMF

SUBSTANTIALLY EQUIVALENT PREDICATE DEVICES:

K072330	Curved Delivery Option & Graft Preparation System (Biomet Biologics, Warsaw, IN)
K043261	Harvest Graft Delivery System (Harvest Technologies Corp., Plymouth, MA)

DEVICE DESCRIPTION:

The FibriJet® Graft Delivery System consists of the Graft Delivery Device, a dual liquid applicator, a blending connector and cups and lids. The Graft Delivery Device itself consists of a syringe barrel, end cap, plunger and funnel.

INDICATIONS FOR USE:

FibriJet® Graft Delivery System is intended for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate the premixing of bone graft materials with fluids such as I.V. fluids, blood, plasma concentrate, platelet rich plasma, bone marrow or other specified blood components deemed necessary by the clinical use requirements.

TECHNOLOGICAL CHARACTERISTICS:

The FibriJet® Graft Delivery System has the same technological characteristics and is similar in overall design, materials and configuration compared to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

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Micromedics, Inc.
% Mr. Tom Lopac
Quality Manager
1270 Eagan Industrial Road
Saint Paul, Minnesota 55121-1385

Re: K100754
Trade/Device Name: FibriJet® Graft Delivery Syringe
Regulation Number: 21 CFR 880.5860
Regulation Name: Piston syringe
Regulatory Class: II
Product Code: FMF
Dated: June 2, 2010
Received: June 3, 2010

Dear Mr. Lopac:

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. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

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/MedicalDevices/Safety/ReportaProblem/default.htm 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 (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,

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

Enclosure

STATEMENT OF INDICATIONS FOR USE

510(k) Number (if known): _____

Device Name: FibriJet® Graft Delivery Syringe

Indications for Use:

FibriJet® Graft Delivery System is intended for the delivery of hydrated allograft, autograft or synthetic bone graft material to an orthopedic surgical site. In addition, it is designed to facilitate the premixing of bone graft materials with fluids such as I.V. fluids, blood, plasma concentrate, platelet rich plasma, bone marrow or other specified blood components deemed necessary by the clinical use requirements.

Prescription Use: ____X_____ OR Over-The-Counter ____ _____
(Per 21 CFT 801.109)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R. Ogden for mxm
(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

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