MAY 10 2010

Revised 510(k) Summary
for *IM*Biotechnologies Ltd.
Occlusin® 500 Artificial Embolization Device
(*per 21CFR 807.92*)

(per 21 CFR 807.92 and http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm)

1. SUBMITTER/510(K) HOLDER

*IM*Biotechnologies Ltd.
Suite 113 – Advanced Technology Centre
Edmonton Research Park
9650 20th Avenue, NW
Edmonton, AB T6N 1G1

Contact Person: Michael W. Stewart
Telephone: 780-945-6609

Date Prepared: May 7, 2010

2. DEVICE NAME

Proprietary Name:	Occlusin® 500 Artificial Embolization Device
Common/Usual Name:	Vascular embolization device
Classification Name:	Device, vascular, for promoting embolization

3. PREDICATE DEVICES

Biosphere Medical Embosphere® (K021397; K991549)

4. DEVICE DESCRIPTION

The Occlusin® 500 Artificial Embolization Device is a collagen-coated polymeric embolization microparticle. It is provided sterile and non-pyrogenic.

5. INTENDED USE

The Occlusin® 500 Artificial Embolization Device is intended to be used as an artificial embolization device in the treatment of unresectable/inoperable hypervascularized tumors.

6. TECHNOLOGICAL CHARACTERISTICS AND SUBSTANTIAL EQUIVALENCE

The claim of substantial equivalence of the Occlusin® 500 Artificial Embolization Device with the cited predicate device is based on indication for use, operational principles, and fundamental design and operational characteristics. The Occlusin® 500 Artificial Embolization Device, like the predicate device, are microspheres delivered to target organs via catheter under angiographic control. Differences in technology were addressed with additional non-clinical testing.

7. SUMMARY OF PERFORMANCE TESTING AS THE BASIS FOR SUBSTANTIAL EQUIVALENCE

Prospectively defined verification and validation testing included biocompatibility testing in compliance with ISO 10993-1; stability testing; catheter compatibility testing; characterization of the finished product to demonstrate compliance with release specifications (including visual examination of appearance, packaging integrity, mass per vial, density, particle count per gram, particle size distribution, residual PVA, molecular weight, collagen content, sterility, endotoxin and melting range; shelf life); and in vivo testing in two animal models. Short term testing (acute and 1 month) was performed in the porcine model and long term testing (3 months, 6 months, and 12 months) was performed in the ovine model. These studies compared the performance of the Occlusin® 500 Artificial Embolization Device with the cited predicate device.

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical testing was conducted to support this submission.

9. SUMMARY OF OTHER INFORMATION

Other information provided in the 510(k) included published studies of embolization.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Design verification and validation testing demonstrate that the Occlusin® 500 Artificial Embolization Device fulfills prospectively defined design specifications. Testing in the two well-accepted animal models shows that the Occlusin® 500 Artificial Embolization Device does not raise new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room W-O66-0609
Silver Spring, MD 20993-0002

MAY 10 2010

*IM*Biotechnologies Ltd.
c/o Ms. Rosina Robinson
Medical Device Consultants, Inc.
49 Plain Street
North Attleboro, MA 02760

Re: K093813
Occlusin® 500 Artificial Embolization Device
Regulation Number: 21 CFR 870.3300
Regulation Name: Vascular Embolization Device
Regulatory Class: Class II
Product Code: KRD
Dated: April 22, 2010
Received: April 26, 2010

Dear Ms. Robinson:

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,

Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K093813

Device Name: Occlusin® Artificial Embolization Device

Indications for Use:

The Occlusin® 500 Artificial Embolization Device is intended to be used as an artificial embolization device in the treatment of unresectable/inoperable hypervascularized tumors.

Prescription Use ___X____ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use___ (21 CFR 807 Subpart C)

(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 Cardiovascular Devices

510(k) Number K093813