

DEC 21 2000

K991093

Changing the tools of surgery**Metamorphic Surgical Devices, LLC**

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Summary of Safety and Effectiveness Information [510(k) Summary]

Submitter Information:	
Submitter's Name:	Metamorphic Surgical Devices, LLC
Address:	660 William Pitt Way Pittsburgh, PA 15238
Phone Number:	(412) 826-5300
Fax Number:	(412) 826-5301
Contact Person:	Gerald Cano, Ph.D.
Contact Person's Address:	660 William Pitt Way Pittsburgh, PA 15238
Date of Preparation:	March 26, 1999
Device Name:	
Trade Name:	MSD™ Embolectomy Basket
Common/Usual Name:	Embolectomy Catheter
Classification Name:	Embolectomy Catheter
Predicate Device Name:	
Trade Name:	Fogarty® Thru-Lumen Embolectomy Catheter Dual Lumen Embolectomy Catheter Biosensor Embolectomy Catheter

Device description:

The MSD™ Embolectomy Basket is a single use basket (not a balloon) for capture and removal of emboli. It has five components: a flexible sack of a bio-compatible material; a wire frame of shape-memory-effect alloy (specifically, Nitinol) in its superelastic state; a bio-compatible sheath; a wire linkage within the sheath connecting the frame to a handle.

The flexible, kink resistant wire linkage slides within the sheath. The proximal ends of both the sheath and the wire linkage are mounted to a handle. The distal end of the wire linkage is attached to the frame. The mouth of the sack, made of a thin, flexible material, is bonded to the loop formed by the frame.

The wire frame can be retracted into the sheath by operation of the handle. This process first closes the mouth of the sack and then configures it for retraction with the frame into the sheath.

660 William Pitt Way • Pittsburgh, PA 15238

Intended Use:

The MSD™ Embolectomy Basket is for use in removal of fresh, soft clot from vessels of the arterial system. NOT for use in the prevention of distal embolization during endovascular interventions. NOT for use in the carotid arteries.

Technical Characteristics Summary:

Parameter	MSD™ Embolectomy Basket	Baxter Fogarty Aterial Embolectoy Catheter
Intended Use	Removing Arterial Emboli	Removing Arterial Emboli
Configuration	Sock-shaped basket with mouth bonded to wire frame retractable into a delivery sheath	Inflatable balloon bonded to a catheter shaft
Deployed Diameter of Basket/Balloon	Basket: 5 mm – 10 mm	Balloon: 4 mm – 14 mm
Catheter Length	65 cm – 120 cm	40 cm – 100 cm
Basket/ Balloon Material	Polyurethane	Latex
Catheter Material	PTFE	Polyvinylchloride
Bonding Material Different from Catheter and Basket/Balloon Material	No	Yes
Use of Inflation Liquid	No	Yes

Performance Testing:

All tests were performed on packaged, sterilized units.

All prescribed biocompatibility tests for a device having short-term exposure to blood were performed by a licensed laboratory under GLP. Results raised no issues relative to material safety.

Bench tests experimentally quantified the structural adequacy of the device. Forces that the human hand must generate to operate the device were measured and shown to be within its force generation capacity. Force levels to separate device components were measured. These were shown to exceed forces experienced by the device under normal operational conditions.

Animal studies were conducted to quantify interactive forces between the basket structure and vascular walls. These were equivalent to those experienced during use of a properly inflated Fogarty catheter. The data was also compared to data from studies in the peer-reviewed literature. Measured force levels raised no safety issues.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 21 2000

Gerald Cano, Ph.D.
President & CEO
Metamorphic Surgical Devices, LLC
660 William Pitt Way
Pittsburg, PA 15238

Re: K991093
Trade Name: MSD Embolectomy Basket
Regulatory Class: II (two)
Product Code: 74 DXE
Dated: October 17, 2000
Received: October 18, 2000

Dear Dr. Cano:

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.

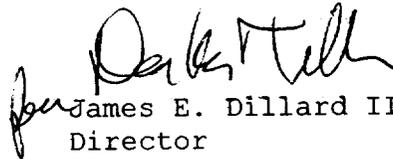
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially 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 pre-market 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.

Page 2 - Gerald Cano, Ph.D.

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) 594-4586. 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,



James E. Dillard III
Director

Division of Cardiovascular and
Respiratory Devices

Office of Device Evaluation

Center for Devices and
Radiological Health

Enclosure

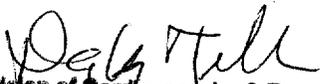
510(k) Number (if known): K991093

Device Name: MSD Embolectomy Basket

Indications For Use: For use in removal of fresh, soft clot from vessels of the arterial system. NOT for use in the prevention of distal embolization during endovascular interventions. NOT for use in the carotid arteries.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)


Division of Cardiovascular & Respiratory Devices
510(k) Number K991093

Prescription Use Only

(Optional Format 3-10-98)