



MAY 31 2002

3600 SW 47th Avenue  
Gainesville, Florida 32608  
TEL: 352/338-0440 FAX: 352/338-0662  
www.mdtech.com

May 13, 2002

**510(k) SUMMARY**      K021606

**APPLICANT:**                      Medical Device Technologies, Inc.  
3600 SW 47<sup>th</sup> Avenue  
Gainesville, FL 32608

**CONTACT:**                         Karl Swartz  
Quality Assurance Manager

**TELEPHONE:**                    (352)338-0440  
fax (352)338-0662

**TRADE NAMES:**                En-Snare™ Endovascular Snare and Catheter

**COMMON NAME:**                Intravascular snare and catheter

**CLASSIFICATION NAME:**        Percutaneous Catheter, 21 CFR 870.1250

**PRODUCT CODE:**                78 DQY

**PANEL:**                            Cardiovascular

**SUBSTANTIAL EQUIVALENCE:**

<u>Company Name</u>	<u>Product Name</u>	<u>510(k) No.</u>
Microvena	Amplatz Goose Neck Snare	K970668 and K972511

**DESCRIPTION OF DEVICE:**

The En-Snare™ Endovascular Snare and Catheter is comprised of stranded nitinol/platinum cables mechanically secured to a nitinol wire inserted into an intravascular catheter and manipulated by use of an external pin vise. The catheter is made from biocompatible FPE that has been used extensively in intravascular catheters.

**INDICATIONS FOR USE:**

The En-Snare™ Endovascular Snare and Catheter is intended for use in the cardiovascular system or hollow viscous to retrieve and manipulate foreign objects. Manipulation procedures include indwelling venous catheter repositioning, indwelling venous catheter fibrin sheath stripping, and central venous access veni-puncture procedure assistance.





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## FUNCTIONAL & SAFETY TESTING:

The En-Snare™ Endovascular Snare and Catheter were subjected to capture function, tip deflection, torqueability, tensile strength, flow rate, hub leakage, and stiffness tests. The results of the testing indicated that they are comparable to the predicate device.

## TECHNICAL COMPARISON:

The following attributes of the En-Snare™ Endovascular Snare and Catheter were examined and found to be comparable to the predicate device:

CATHETER	SNARE
1. Intended use	1. Intended use
2. French Sizes	2. Sizes
3. Length	3. Length
4. Lumens	4. Distal end configuration
5. Distal end configuration	5. Intended anatomical location of distal end
6. Intended anatomical location of distal end	6. Proximal end configuration
7. Proximal end configuration	7. Materials
8. Materials	8. Labeling
9. Labeling	





Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

**MAY 31 2002**

Medical Device Technologies, Inc  
c/o Mr. N.E. Devine, Jr.  
Entela, Inc.  
3033 Madison Ave, SE  
Grand Rapids, MI 49548

Re: K021606  
En-Snare™ Endovascular Snare and Catheter  
Regulation Number: 870.5150  
Regulation Name: Embolectomy Catheter  
Regulatory Class: Class II (two)  
Product Code: 74 MMX  
Dated: May 13, 2002  
Received: May 16, 2002

Dear Mr. Devine:

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 such 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);

Page 2 - Mr. N.E. Devine, Jr.

labeling (21 CFR Part 801); 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.

This letter will allow you to begin marketing your device as described in your Section 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 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4646. 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 Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer 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,



Donna-Bea Tillman, Ph.D.  
Acting Director  
Division of Cardiovascular  
and Respiratory Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure



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510(k) Number (if known): K021606

Device Name: En-Snare™ Endovascular Snare and Catheter

Indications for Use:

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

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Concurrence of CDRH, Office of Device Evaluation (ODE)

*Dalbert*  
 Division of Cardiovascular & Respiratory Devices  
 510(k) Number K021606

Prescription Use   
 (Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)

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MEDICAL DEVICE TECHNOLOGIES INC.

