

K070197

**5. 510(k) Summary**

General Information

FEB 23 2007

Date Compiled January 19 2007  
 Classification Class II,  
 Trade Name Acumen Lead Delivery Sheath with Stylet  
 Submitter Acumen Medical, Inc.  
 275 Santa Ana Court  
 Sunnyvale, CA 94085  
 Tel: 408-530-1810  
 Fax: 408-530-1811

Contact Marybeth Gamber  
 Director, Regulatory Affairs

Intended Use

The Acumen Lead Delivery Sheath with Stylet is indicated for the introduction of various types of pacing or defibrillator leads and catheters.

Predicate Devices

Acumen Lead Delivery Sheath  
 Manufactured by Acumen Medical, Inc. K062145

Device Description

The Acumen Lead Delivery Sheath with Stylet is a single-use percutaneous catheter intended to introduce various types of pacing or defibrillator leads and catheters. The Acumen Lead Delivery Sheath with Stylet has a guidewire lumen and a lumen for introduction of leads. The Acumen Lead Delivery Sheath with Stylet will be packaged with a stylet to aid in positioning of the device in the vasculature.

Materials

All materials used in the manufacture of the Acumen Lead Delivery Sheath with Stylet are suitable for this use and have been used in numerous previously cleared products.

Testing

Appropriate testing has been performed and all components, subassemblies, and/or full devices met the required specifications for the completed tests.

Summary of Substantial Equivalence

Acumen Medical, Inc. believes the Acumen Lead Delivery Sheath with Stylet is substantially equivalent to the predicate product. The intended use, method of operation, methods of construction and materials used, are either identical or substantially equivalent to existing legally marketed predicate product.



Food and Drug Administration  
9200 Corporate Boulevard  
Rockville MD 20850

FEB 23 2007

Acumen Medical, Inc.  
C/O Marybeth Gamber  
275 Santa Ana Court  
Sunnyville, CA 94085

Re: K070197

Trade/Device Name: Acumen Lead Delivery Sheath with Stylet  
Regulation Number: 21 CFR 870.1340  
Regulation Name:  
Regulatory Class: Class II  
Product Code: DYB  
Dated: January 19, 2007  
Received: January 23, 2007

Dear Ms. Gamber:

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.

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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); 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), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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,



Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and

Radiological Health

Enclosure

**4. Indications for Use Statement**

510(k) Number (if known): This application

Device Name: Acumen Lead Delivery Sheath with Stylet

Indications for Use: The Acumen Lead Delivery Sheath with Stylet is indicated for the introduction of various types of pacing or defibrillator leads and catheters.

Prescription Use  X   
(Per 21 CFR 801 Subpart D)

AND/OR

Over-The-Counter Use \_\_\_\_\_  
(Per 21 CFR 801 Subpart C)

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)

  
\_\_\_\_\_  
(Division Sign-Off)  
Division of Cardiovascular Devices  
510(k) Number  K070197