



October 23, 2015

NeoMetrics, Inc.  
Mr. David Liebl  
President and Chief Technology Officer  
2605 Fernbrook Lane North, Suite J  
Plymouth, MN 55447

Re: K152560  
Trade/Device Name: Bard<sup>®</sup> Snare Retrieval Kit  
Regulation Number: 21 CFR 870.5150  
Regulation Name: Embolectomy Catheter  
Regulatory Class: Class II  
Product Code: MMX  
Dated: September 8, 2015  
Received: September 9, 2015

Dear Mr. Liebl:

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 contact the Division of Industry and Consumer Education 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>. 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 Industry and Consumer Education 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,

**Kenneth J. Cavanaugh -S**

for

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

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES  
Food and Drug Administration

Form Approved: OMB No. 0910-0120  
Expiration Date: January 31, 2017  
See PRA Statement below.

## Indications for Use

510(k) Number (if known)

K152560

Device Name

Bard® Snare Retrieval Kit

Indications for Use (Describe)

The Bard® Snare Retrieval Kit is intended for use to percutaneously remove all Bard optional vena cava filters with a retrieval hook.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

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

### CONTINUE ON A SEPARATE PAGE IF NEEDED.

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**6.0 510(K) SUMMARY**

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Applicant: NeoMetrics, Inc.  
2605 Fernbrook Lane North, Suite J  
Plymouth, MN 55447

Contact Person: Dave Liebl, President and Chief Technology Officer  
2605 Fernbrook Lane North, Suite J  
Plymouth, MN 55447

Date Prepared: September 8, 2015

Trade Name: Bard® Snare Retrieval Kit

Common or Usual Name: Device, Percutaneous Retrieval

Classification: Class II  
Regulation Number: 21 CFR 870.5150

Product Code: MMX

Review Panel: Cardiovascular Devices

Predicate Device: The subject device is substantially equivalent to K073374; Günther Tulip™ Vena Cava Filter Retrieval Set manufactured by Cook Medical.

Device Description: The Bard® Snare Retrieval Kit is intended to percutaneously remove Bard filters from the vena cava.  
The Bard® Snare Retrieval Kit consists of a Nitinol Snare with 6 French Snare Catheter Assembly and a 11 French O.D Retrieval Sheath with 9 French Dilator Assembly.  
The nitinol snare has a 20 mm diameter (fully expanded) radiopaque loop and comes preloaded in the snare catheter. The snare catheter, retrieval sheath, and access sheath have radiopaque marker bands at the distal ends for enhanced fluoroscopic visualization.

Indication for Use: The Bard® Snare Retrieval Kit is intended for use to percutaneously remove all Bard optional vena cava filters with a retrieval hook.

Principle and Mechanism of Operation: Mechanically snare the hook of the Vena Cava Filter, advance the sheath to collapse the filter and remove.

Functional and Safety Testing:	<p>To verify that device design meets functional and performance requirements, representative samples of the device underwent bench testing in accordance with applicable standards and guidance. These data provide an acceptable assurance of the safety and effectiveness of the Bard® Snare Retrieval Kit and demonstrate the device is equivalent to the predicate.</p>
Comparative Technology Characteristics	<p>A comparison of the characteristics of the proposed device and the predicate device shows the Bard® Snare Retrieval Kit to have the same technological characteristics to the predicate which has received 510(k) clearance.</p> <p>Equivalence is based upon intended use, indications for use, operating principle and fundamental scientific technology. Both devices are catheter based systems that have collapsible wires for filter engagement and withdrawal into an outer sheath. Both systems are designed to be used over a guidewire. Both devices contain marker bands for visibility and both have similar dimensions. Both devices have similar materials of construction, dimensions, and designs. Minor difference does exist in dimensions and material. These minor differences in technological characteristics do not raise different questions of safety and effectiveness.</p>
Non-Clinical Tests Submitted	<p>The following tests were performed to support Bard® Snare Retrieval Kit's substantial equivalence.</p> <ul style="list-style-type: none"> <li>○ Performance Testing, including: <ul style="list-style-type: none"> <li>• Catheter Tensile Strength</li> <li>• Catheter Liquid Leakage</li> <li>• Catheter Corrosion Resistance</li> <li>• Snare Assembly Torque Strength</li> <li>• Snare Simulated Use</li> </ul> </li> <li>○ Biocompatibility Testing, including: <ul style="list-style-type: none"> <li>• Cytotoxicity (ISO 10993-5)</li> <li>• Sensitization (ISO 10993-10)</li> <li>• Irritation - Intracutaneous Reactivity (ISO10993-10)</li> <li>• Acute Systemic Toxicity (ISO10993-11)</li> <li>• Pyrogenicity (ISO 10993-11)</li> <li>• Hemocompatibility</li> <li>• Thromboresistance</li> <li>• Coagulation (ISO 10993-4)</li> </ul> </li> </ul>
Conclusion:	<p>NeoMetrics Inc. considers the Bard® Snare Retrieval Kit to be equivalent to the predicate device. This conclusion is based upon the fact that device has an equivalent intended use, and there are no differences that raise new types of questions of safety and effectiveness.</p>