K131475



### 5. 510(k) Summary of safety and effectiveness

This 510(k) summary of safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

| | |
|---|---|
| **APPLICANT:** | Blockade Medical |
| **DATE PREPARED:** | June 24, 2013 |
| **CONTACT PERSON:** | Rebecca K Pine<br>Blockade Medical<br>18 Technology Dr.<br>Suite 169<br>Irvine, CA 92618<br>Phone: (760) 809.5178 |
| **TRADE NAME:** | Barricade Embolization Coil System |
| **COMMON NAME:** | Neurovascular embolization device |
| **CLASSIFICATION NAME:** | Neurovascular embolization device |
| **DEVICE CLASSIFICATION:** | Class 2, per 21 CFR 882.5950 |
| **PRODUCT CODE** | HCG |
| **PREDICATE DEVICES:** | Barricade Embolization Coil System (K123338) |

JUL 25 2013

**Substantially Equivalent To:**
The modified Barricade Embolization Coil System is substantially equivalent in intended use, principal of operation and technological characteristics to the Barricade Embolization Coil System cleared under premarket notification K123338.

**Description of the Device Subject to Premarket Notification:**
The Barricade Embolization Coil System (BCS) is a series specialized coils that are inserted into the vasculature under angiographic visualization to embolize intracranial aneurysms and other vascular anomalies. The system consists of an embolization coil implant comprised of platinum/tungsten, affixed to a delivery pusher with an introducer sheath to facilitate insertion into the hub of a microcatheter. The system is available in various shapes, lengths and sizes. The devices are to be placed into aneurysms to create blood stasis, reducing flow into the aneurysm and thrombosing the aneurysm. Upon positioning coils into the aneurysm, the coils are electrolytically detached from the delivery pusher in serial manner until the aneurysm is occluded.

**Indication for Use:**
The Barricade Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations

and arteriovenous fistulae. The Barricade Coil System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

**Technical Characteristics:**
The Barricade Embolization Coil System has similar physical and technical characteristics to the predicate device as outlined in the table below:

| | Barricade Embolization Coil System | Barricade Embolization Coil System (K123338) |
|---|---|---|
| | Facilitates endovascular embolization of intracranial aneurysms and other vascular abnormalities | SAME |
| Primary Coil Diameter | 0.010"-0.014" | SAME |
| Coil Secondary diameter | 1.5mm – 15mm | SAME |
| Coil Wire Diameter | 0.00125"-0.003" | SAME |
| Secondary Shapes | Complex/Helical | SAME |
| Coil Types | Framing, Filling, Finishing | SAME |
| Coil length | 1cm – 40cm | SAME |
| Main Coil Material | Platinum/Tungsten alloy | SAME |
| Coil delivery | Stainless steel wire/pusher | SAME |
| Coil detachment | Electrolytic | SAME |
| Detachment equipment | Detachment Control Power Supply, ED2-BL | SAME |
| Method of supply (coil/delivery system) | Sterile, single use | SAME |
| Delivery Wire | .012" dia SSTL<br>100005-005 | .010" dia. SSTL<br>100005-001 |
| Labeled Sizes (coils) | 10Framing<br>New sizes:<br>4mm x13cm<br>5mm x 17cm<br>6mm x 20cm<br>7mm x 24cm<br>8mm x 27cm<br>9mm x 30cm<br>10mm x 34cm<br><br>18 Framing<br>6mm x 20cm<br>7mm x 24cm<br>8mm x 27cm<br>9mm x 30cm<br>10mm x 34cm<br>11mm x 37cm<br>12mm x 40cm<br>13mm x 43cm<br>14mm x 47cm<br>15mm x 50cm | 10 Framing<br>2mm – 10mm x 3cm-27cm<br><br>18 Framing<br>6mm – 15mm x 16cm-50cm<br><br>Filling<br>3mm – 10mm x 4cm – 40cm<br><br>Finishing<br>1.5mm - 6mm x 1cm – 10cm |

| | | |
|---|---|---|
| | Filing<br>4mm x 15cm<br>4mm x 20cm<br>5mm x 20cm<br>5mm x 25cm<br>6mm x 25cm<br>6mm x 30cm<br>10mm x 40cm<br><br>Finishing<br>1.5mm x 4cm<br>1.5mm x 6cm<br>2mm x 6cm<br>2mm x 8 cm<br>2.5mm x 8cm<br>3mm x 8cm<br>3mm x 10cm<br>4mm x 10cm | |

The modified Barricade Coil System and predicate Barricade Coil System devices differ in the following:

- Additional sizes added to product family
- Change in delivery wire diameter

**Performance Data:**

All necessary verification and validation testing has been performed for the Barricade Embolization Coil System to assure substantial equivalence to the predicate devices and demonstrate the device performs as intended. All testing was performed on test units representative of finished devices. Comparative simulated use testing demonstrated that the Barricade Embolization Coil System is substantially equivalent to the predicate devices. Testing included:

- Visual inspection
- Dimensional measurement
- Simulated Use
    - Introduction
    - Tracking
    - Reposition/deployment
    - Detachment
    - Overall Performance
- Detachment Zone tensile

The modified Barricade Coil System met all specified criteria and did not raise new safety or performance questions.

**Basis for Determination of Substantial Equivalence:**

The Indication/Intended Use and the fundamental scientific technology of the modified device have not been changed and are the same as those described in the unmodified predicate device. The modified Barricade Coil System is determined by Blockade Medical, to be substantially equivalent to the Barricade Coil System (K123338).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

July 25, 2013

Ms. Rebecca K. Pine
Blockade Medical
18 Technology Drive, Suite 169
Irvine, CA 92618

Re: K131475
Trade/Device Name: Barricade Embolization Coil System
Regulation Number: 21 CFR 882.5950
Regulation Name: Neurovascular embolization device
Regulatory Class: Class II
Product Code: HCG
Dated: June 24, 2013
Received: June 26, 2013

Dear Ms. Pine:

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 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. 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,

Victor Krauthamer -S

Victor Krauthamer, Ph.D.
Acting Director
Division of Neurological
and Physical Medicine Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

# Indications for Use

510(k) Number (if known): K131475

Device Name: Barricade Embolization Coil System

Indications For Use:

The Barricade Coil System is intended for the endovascular embolization of intracranial aneurysms and other neurovascular abnormalities such as arteriovenous malformations and arteriovenous fistulae. The Barricade Coil System is also intended for vascular occlusion of blood vessels within the neurovascular system to permanently obstruct blood flow to an aneurysm or other vascular malformation and for arterial and venous embolizations in the peripheral vasculature.

Prescription Use X (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

---

Concurrence of CDRH, Office of Device Evaluation (ODE)

Victor Krauthamer -S
2013.07.25 18:20:24 -04'00'

(Division Sign Off)
Division of Neurological and Physical Medicine Devices (DNPMD)

510(k) Number K131475