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

January 23, 2015

Amsel Medical Corporation
% Leo Basta
NorthStar Biomedical Associates
93 Benefit Street
Providence, Rhode Island 02904

Re: K140932
  Trade/Device Name: Amsel Occluder Device
  Regulation Number: 21 CFR 878.4300
  Regulation Name: Implantable clip
  Regulatory Class: Class II
  Product Code: FZP
  Dated: November 28, 2014
  Received: December 1, 2014

Dear Leo Basta:

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" (21 CFR 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,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure
INDICATIONS FOR USE STATEMENT

510(k) Number (if known): K140932

Device Name: Amsel Occluder Device

Indications for Use:
The Amsel Occluder Device is intended for use in open general surgery procedures on tubular structures or vessels wherever a metal ligating clip is indicated and within the size range of 2.0mm to 7.0mm diameter.

Prescription Use ✓ AND/OR Over-The-Counter Use

(Please do not write below this line -- continue on another page if needed)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Amsel Medical Corp. Rev A
Traditional Premarket Notification Submission – 510(k)

510(k) SUMMARY
Amsel Occluder Device

510(k) Number K362; 54

Prepared January 22, 2015

5.1 Company Name
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5.2 Contact Person
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Tel: 972-7453607
Fax: 972-153-9-7453607
oram.ma@gmail.com

5.3 Trade/Proprietary Name
Amsel Occluder Device

5.4 Classification Name
Clip Implantable

5.5 Product Code/Regulation No.
Product code: FZP, Regulation No. 878.4300.

Amsel Medical Corp. Rev A
5.6 Device Classification
   Class II

5.7 Panel
   General & Plastic Surgery

5.8 Predicate Devices
   2. Ethicon Inc. LigaClip, cleared under K834267 (product code FZP, Regulation No. 878.4300).

5.9 Intended Use
   The Amsel Occluder Device involves the implantation of a mechanical occlusion device that penetrates into and through the target vessel structure and when compressed and locked, clamps the vessel shut.

5.10 Device Description
   The Amsel Occluder Device involves the implantation of a mechanical occlusion device that penetrates into and through the target vessel structure and when compressed and locked, clamps the vessel shut.

5.11 Substantial Equivalence
   The Amsel Occluder Device is substantially equivalent to the legally marketed predicate devices for the following reasons:
   - The Amsel Occluder Device has the same intended use and similar indications for use as the predicate devices,
- All devices use similar technology to deliver a clip to mechanically compress the tissue,
- The Amsel Occluder employs similar or the same materials as its predicates,
- The Amsel Occluder and the predicate devices use a delivery applicator that offers smooth, efficient deployment of the clip/s, and
- All three devices share similar dimensional attributes.

The following table contains a summary of the descriptive and technological characteristics of the Amsel Occluder Device compared to the predicate devices.
<table>
<thead>
<tr>
<th><strong>AMS EL OCCLUDER DEVICE</strong></th>
<th><strong>TWISTER SUPERELASTIC LIGATING CLIP</strong></th>
<th><strong>LIGACLIP</strong></th>
<th><strong>SE</strong></th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>510(k) Number</strong></td>
<td>Not yet known</td>
<td>K032238</td>
<td>K834267</td>
</tr>
<tr>
<td><strong>Manufacturer</strong></td>
<td>Amsel Medical Corp.</td>
<td>Neurosel Medical Ltd.</td>
<td>Ethicon Inc.</td>
</tr>
<tr>
<td><strong>Product Code</strong></td>
<td>FZP</td>
<td>FZP</td>
<td>FZP</td>
</tr>
<tr>
<td><strong>CFR</strong></td>
<td>878.4300</td>
<td>878.4300</td>
<td>878.4300</td>
</tr>
<tr>
<td><strong>Intended Use &amp; Indications for Use</strong></td>
<td>The Amsel Occluder Device is intended for use in open general surgery procedures on tubular structures or vessels wherever a metal ligating clip is indicated and within the size range of 2.0mm to 7.0mm diameter. The Twister Superelastic Ligating Clip, Size M is intended for the permanent occlusion or ligation of blood vessels and other tubular body structures, wherever a metal ligating clip is indicated, and within the size range of 2.0 to 3.5mm diameter. The LIGACLIP MULTIPLE CLIP APPLIER is intended for use on tubular structures or vessels wherever a metal ligating clip is indicated. The tissue being ligated should be consistent with the size of the clip. Similar. Size range for the Amsel Occluder was demonstrated through animal testing performed using the device.</td>
<td></td>
<td></td>
</tr>
<tr>
<td><strong>Pre Loaded \ Loaded in OR</strong></td>
<td>Pre-loaded</td>
<td>Pre-loaded</td>
<td>Loaded in the OR</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Same as Neurosel</td>
</tr>
</tbody>
</table>

Amsel Medical Inc. Rev A
<table>
<thead>
<tr>
<th>AMSEL OCCLUDER DEVICE</th>
<th>TWISTER SUPERELASTIC LIGATING CLIP</th>
<th>LIGA CLIP</th>
<th>SE</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>Clip Size</strong></td>
<td>One size</td>
<td>S,M,L</td>
<td>M,O/N L</td>
</tr>
<tr>
<td><strong>Vessel Size</strong></td>
<td>2.0mm-7.0mm</td>
<td>2.0mm-3.5mm (M)</td>
<td>2.0mm-6.0mm</td>
</tr>
<tr>
<td><strong>Length of clip</strong></td>
<td>5.7mm</td>
<td>unknown</td>
<td>5.5mm</td>
</tr>
<tr>
<td><strong>Secured to vessel or tubular structure</strong></td>
<td>Mechanical, by compressing the clip components (sliding and locking two nitinol elements one against the other on either side of the vessel and locked together with a titanium rod)</td>
<td>Mechanical compression</td>
<td>Mechanical compression</td>
</tr>
<tr>
<td><strong>Closure method</strong></td>
<td>Penetrating through (transfixing) the vessel using a needle and then deploying locking the vessel externally</td>
<td>External vessel compression</td>
<td>External vessel compression</td>
</tr>
<tr>
<td><strong>AMSEL OCCLUDER DEVICE</strong></td>
<td><strong>TWISTER SUPERELASTIC LIGATING CLIP</strong></td>
<td><strong>LIGACLIP</strong></td>
<td><strong>SE</strong></td>
</tr>
<tr>
<td>--------------------------</td>
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<td>-------</td>
</tr>
<tr>
<td><strong>Clip Material</strong></td>
<td>Nitinol and titanium</td>
<td>Nitinol</td>
<td>Titanium</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Similar. Amsel uses the same and additional material. All materials tested for biocompatibility and functionality and any differences do not adversely affect safety or effectiveness.</td>
</tr>
<tr>
<td><strong>Single Patient Use, Disposable</strong></td>
<td>Yes</td>
<td>Yes</td>
<td>Yes</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Same</td>
</tr>
<tr>
<td><strong>Sterilization</strong></td>
<td>Sterile for single use EtO</td>
<td>Sterile for single use EtO</td>
<td>Sterile for single use EtO</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Same</td>
</tr>
<tr>
<td><strong>Prescription Use</strong></td>
<td>Yes. The device should be used only by trained surgeon.</td>
<td>Yes. The device should be used only by trained surgeon.</td>
<td>Yes. The device should be used only by trained surgeon.</td>
</tr>
<tr>
<td></td>
<td></td>
<td></td>
<td>Same</td>
</tr>
</tbody>
</table>
As demonstrated in the completed battery of preclinical tests that were conducted by the company minor technological differences between the Amsel Occluder Device and the predicate devices do not raise new questions of safety and effectiveness. Any minor differences in technological characteristics have been tested and reported on in this notification and demonstrate that such differences do not adversely affect the safety, effectiveness, or intended performance of the device. Therefore, the Amsel Occluder Device is substantially equivalent to the legally marketed predicate devices. Testing in support of the SE determination included laboratory bench testing, biocompatibility testing, shelf life testing and animal testing.

5.12 Performance Characteristics of the Amsel Occluder Device

The Amsel Occluder Device underwent a full battery of bench testing and animal testing to demonstrate its safe and effective performance in occluding vessels. It was concluded that the device is safe and effective for its intended use. Tests were performed in comparison to the predicate device. Specifically, testing included:

- **Clip Closure Distance**
  - to verify Clip closure distance to ensure it is within the designed specification

- **Clip Closure Repeatability and Reliability**
  - to verify the repeatable compression and locking of the occluder clip

- **Strain Analysis**
  - the purpose was to analyze the maximal strain of the clips during occlusion

- **Corrosion Test**
  - Verification that the device does not develop corrosion post implantation

- **Performance Evaluation**
  - to verify the performance of the Amsel Occluder device in a simulated model

- **Device to Implant Detachment Force**
  - to verify that the force required to detach the clip from the delivery system is sufficiently robust to prevent inadvertent detachment of the delivery system from the clip

- **Holding Pressure Evaluation**
  - verification of occlusion performance by pressurizing occluded structure through pressures over 700mmHg

- **Release Mechanism Function Testing**
  - to verify proper detachment of the delivery system from the implant during operation
• Deployment Force Testing
  - The force required to deploy the Amsel Occluder Device was tested in comparison to a predicate. Results were that the Amsel device took less force than the predicate to deploy the device

• Biocompatibility Testing
  - to verify that all body contact materials are biocompatible for the contact and duration of contact

• Animal study including holding pressure and histology
  - preclinical in-vivo use of the Amsel device compared to a predicate device to evaluate the safety and effectiveness of the Amsel device in terms of introduction, deployment, usability, and occlusion performance

• MR Imaging Testing
  - to support the MR conditional claim in the device's labeling.

All testing performed demonstrated that the Amsel Occluder is a safe and effective device for vessel and tubular structure occlusion and is considered substantially equivalent to its predicate devices.

5.13 Conclusion
Amsel Medical believes that, based on the descriptive information and testing provided in this submission, the Amsel Occluder Device is substantially equivalent to its predicate devices.