October 31, 2018

SOMATEX Medical Technologies GmbH
Burkhard Jakob
Regulatory Affairs Manager
Rheinstrasse 7d, Teltow, DE 14513 Brandenburg
GERMANY

Re: K182082
  Trade/Device Name: Tumark for Eviva, Tumark for Brevera
  Regulation Number: 21 CFR 878.4300
  Regulation Name: Implantable Clip
  Regulatory Class: Class II
  Product Code: NEU
  Dated: July 24, 2018
  Received: August 2, 2018

Dear Dr. Jakob:

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. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database located at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. 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) for devices or postmarketing safety reporting (21 CFR 4, Subpart B) for combination products (see https://www.fda.gov/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR 820) for devices or current good manufacturing practices (21 CFR 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

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 comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Joseph Nielsen -S

Digitally signed by Joseph Nielsen -S
DN: c=US, o=U.S. Government, ou=HHS, ou=FDA, ou=People, cn=Joseph Nielsen -S,
0.9.342.19200300.100.1.1=200036750
5
Date: 2018.10.31 09:43:45 -04'00'

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

510(k) Number (if known)
K182082

Device Name
Tumark for Eviva
Tumark for Brevera

Indications for Use (Describe)
Tumark for Eviva and Tumark for Brevera are intended to attach a marker to soft tissue at the surgical site during a percutaneous procedure. The devices are indicated for use to radiographically and radiologically mark the surgical location in breasts following a percutaneous procedure. They are not indicated to be used with magnetic resonance imaging (MRI) techniques.
510(k) Summary
Tumark for Eviva and Tumark for Brevera

DATE PREPARED: 24.07.2018

APPLICANT: SOMATEX Medical Technologies GmbH
Rheinstrasse 7d
14513 Teltow
GERMANY
Tel: +49 30 319 82 25 00
Fax: +49 30 319 82 25 99
E-Mail: service@somatex.com

CONTACT PERSON: Burkhard Jakob, PhD
Regulatory Affairs Manager
Tel.: +49 30 319 82 25-51
E-Mail: B.Jakob@somatex.com
1 Device Name

Trade Name: Tumark for Eviva  
Tumark for Brevera

Common Name: Tissue Site Marking System

Device Classification Name: Marker, Radiographic, Implantable

2 Classification / Product Code

The Tumark for Eviva and Tumark for Brevera can be classified according to following device name and product code:

<table>
<thead>
<tr>
<th>Device</th>
<th>Regulation Description</th>
<th>Regulation Medical Specialty</th>
<th>Review Panel</th>
<th>Product Code</th>
<th>Regulation Number</th>
<th>Device Classification</th>
</tr>
</thead>
<tbody>
<tr>
<td>Marker, Radiographic, Implantable clip</td>
<td>Implantable clip</td>
<td>General &amp; Plastic Surgery</td>
<td>General &amp; Plastic Surgery</td>
<td>NEU</td>
<td>878.4300</td>
<td>2</td>
</tr>
</tbody>
</table>

3 Predicate Device / Reference Device

<table>
<thead>
<tr>
<th>Device</th>
<th>Predicate Device (Reference Device)</th>
<th>510(k) Number</th>
<th>SIO(k) Holder</th>
</tr>
</thead>
<tbody>
<tr>
<td>Tumark for Eviva</td>
<td>Tumark Professional (Tumark Vision)</td>
<td>K093064</td>
<td>SOMATEX Medical Technologies GmbH</td>
</tr>
<tr>
<td>Tumark for Brevera</td>
<td></td>
<td>(K180443)</td>
<td></td>
</tr>
</tbody>
</table>

4 Device Description

Tumark for Eviva and Tumark for Brevera are sterile, single use, preloaded tissue site marking systems consisting of a non-absorbable nickel-titanium marker, an introducer cannula and a plastic handheld applier with deployment mechanism.

The introducer cannula has a blunt tip and can only be used together with an introducer. The handle is equipped with a slide-button which allows for a one handed placement of the marker by pressing it forward. A safety catch system prevents the slide-button to inadvertently move forward and therefore prevents a premature deployment of the marker.

5 Intended Use

Tumark for Eviva and Tumark for Brevera are intended to attach a marker to soft tissue at the surgical site during a percutaneous procedure. The devices are indicated for use to radiographically and radiologically mark the surgical location in breasts following a
percutaneous procedure. They are not indicated to be used with magnetic resonance imaging (MRI) techniques.

6 Technological Characteristics

<table>
<thead>
<tr>
<th>Description</th>
<th>SOMATEX Medical Technologies (New Device)</th>
<th>SOMATEX Medical Technologies (Predicate Device)</th>
<th>SOMATEX Medical Technologies (Reference Device)</th>
</tr>
</thead>
<tbody>
<tr>
<td>Regulation Number</td>
<td>878.4300</td>
<td>878.4300</td>
<td>878.4300</td>
</tr>
<tr>
<td>Class</td>
<td>2</td>
<td>2</td>
<td>2</td>
</tr>
<tr>
<td>Product Code</td>
<td>NEU</td>
<td>NEU</td>
<td>NEU</td>
</tr>
<tr>
<td>Design</td>
<td>Sterile, single use, preloaded tissue site marking systems consisting of a non-absorbable nickel-titanium marker, an introducer cannula and a plastic handheld applier with deployment mechanism.</td>
<td>Sterile, single use, preloaded tissue site marking systems consisting of a non-absorbable nickel-titanium marker, an introducer cannula and a plastic handheld applier with deployment mechanism.</td>
<td>Sterile, single use, preloaded tissue site marking systems consisting of a non-absorbable nickel-titanium marker, an introducer cannula and a plastic handheld applier with deployment mechanism.</td>
</tr>
<tr>
<td>Marker</td>
<td>X-, Q- or sphere-shaped design which is visible in ultrasound, mammography and MRI</td>
<td>Li-shaped or X-shaped visible in ultrasound, mammography and MRI</td>
<td>Sphere-shaped design which is visible in ultrasound, mammography and MRI</td>
</tr>
<tr>
<td>Marker Material</td>
<td>Nitinol</td>
<td>Nitinol</td>
<td>Nitinol</td>
</tr>
<tr>
<td>Cannula Design</td>
<td>Blunt, rounded tip no markings</td>
<td>Sharp tip with ultrasound enhancement on the distal end, markings on the cannula and puncture function</td>
<td>Sharp tip with ultrasound enhancement on the distal end, markings on the cannula and puncture function</td>
</tr>
<tr>
<td>Cannula length [mm]</td>
<td>123.5/125.5/127.5/129.5/132.0/133.0/135.5</td>
<td>100 / 120</td>
<td>100 / 120</td>
</tr>
<tr>
<td>Cannula Diameter [mm]</td>
<td>1.2</td>
<td>1.2</td>
<td>1.2</td>
</tr>
<tr>
<td>Gauge [G]</td>
<td>18</td>
<td>18</td>
<td>18</td>
</tr>
<tr>
<td>Cannula Material</td>
<td>stainless steel</td>
<td>stainless steel</td>
<td>stainless steel</td>
</tr>
<tr>
<td>Handle</td>
<td>One-handed application with safety function to prevent premature deployment of the marker</td>
<td>One-handed application with safety function to prevent premature deployment of the marker</td>
<td>One-handed application with safety function to prevent premature deployment of the marker</td>
</tr>
<tr>
<td>Handle Material</td>
<td>stainless steel and plastic</td>
<td>stainless steel and plastic</td>
<td>stainless steel and plastic</td>
</tr>
<tr>
<td>Sterilization Method</td>
<td>Ethylene oxide</td>
<td>Ethylene oxide</td>
<td>Ethylene oxide</td>
</tr>
</tbody>
</table>

7 Performance Data

To demonstrate that the new devices are as safe and effective as the predicate device Tumark Professional, its technological characteristics and performance criteria were evaluated. The new devices were evaluated in bench and in vitro testing. Specific aspects included:
<table>
<thead>
<tr>
<th>Aspect</th>
<th>Test Method</th>
<th>Result</th>
</tr>
</thead>
<tbody>
<tr>
<td>Biocompatibility</td>
<td>Testing per ISO-10993-1</td>
<td>Device met required biocompatibility requirements. All acceptance criteria met.</td>
</tr>
<tr>
<td>Sterility</td>
<td>Testing per ISO 11737-1 and ISO 11737-2</td>
<td>Device can be sterilized by the sterilization process. All acceptance criteria met.</td>
</tr>
<tr>
<td>Shelf life</td>
<td>Confirm the function of the device after accelerated and real-time aging</td>
<td>Device performance is maintained after simulated aging conditions. All acceptance criteria met.</td>
</tr>
<tr>
<td>Blunt cannula tip</td>
<td>Confirm that cannula does not damage wall of introducer sheath</td>
<td>The introducer sheath was undamaged after placing the marker. The marker could be placed at the intended location. All acceptance criteria met.</td>
</tr>
<tr>
<td>Cannula is compatible with introducers of respective vacuum biopsy systems</td>
<td>Confirm that marker can be deployed into the target region</td>
<td>The marker could be placed at the intended location. All acceptance criteria met.</td>
</tr>
<tr>
<td>Functionality of protection tube</td>
<td>Confirm that cannula lies within removable protection tube after being removed out of the blister</td>
<td>The protection tube does not fall off by itself during handling but can be removed manually from the cannula. All acceptance criteria met.</td>
</tr>
<tr>
<td>Device Performance</td>
<td>Confirm that marker can be placed in the target area</td>
<td>X-, Q-, and Vision markers could be deployed into the breast phantom. The device performs as intended. All acceptance criteria met.</td>
</tr>
</tbody>
</table>

The results from bench testing demonstrate that the different technological characteristics do not raise questions concerning safety and effectiveness. The new device can be used safely and effectively.

8 Substantial Equivalence Summary / Conclusion
The proposed changes do not raise any new questions regarding safety and effectiveness of the Tumark for Eviva and Tumark for Brevera. Tumark for Eviva and Tumark for Brevera are substantially equivalent to the predicate device Tumark Professional.