March 22, 2018

SOMATEX Medical Technologies GmbH
Burkhard Jakob, M.D.
Regulatory Affairs Manager
Rheinstr. 7d
Teltow, Brandenburg 14513
Germany

Re: K180443
Trade/Device Name: Tumark Vision
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: February 13, 2018
Received: February 20, 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. 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.

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.

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,

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K180443

Device Name
Tumark Vision

Indications for Use *(Describe)*
The Tumark Vision is intended to attach a marker to soft tissue at the surgical site during an open or a percutaneous procedure. It is indicated for use to radiographically and radiologically mark the surgical location in breasts following an open or percutaneous procedure. It is not intended to be used with magnetic resonance imaging (MRI) techniques.

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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510(k) SUMMARY
Tumark Vision

DATE PREPARED: 02.03.2018

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1 Device Name

Trade Name: *Tumark Vision*

Common Name: *Tissue Site Marking System*

Device Classification Name: *Marker, Radiographic, Implantable*

2 Classification / Product Code

The Tumark Vision can be classified according to following device name and product code:

Device	Regulation Description	Regulation Medical Specialty	Review Panel	Product Code	Regulation Number	Device Classification
Marker, Radiographic, Implantable	Implantable clip	General & Plastic Surgery	General & Plastic Surgery	NEU	2	878.4300

3 Predicate Device / Reference Device

Device	Predicate Device	510(k) Number	510(k) Holder
Tumark Vision	Tumark Professional	K093064	SOMATEX Medical Technologies GmbH

4 Device Description

The Tumark Vision is a sterile, single use, preloaded tissue site marking system consisting of a non-absorbable nickel-titanium marker, an introducer cannula and a plastic handle. It is intended to attach a marker to soft tissue at the surgical site during an open or a percutaneous procedure. It is indicated for use to radiographically and radiologically mark the surgical location in breasts following an open or percutaneous procedure. It is not intended to be used with magnetic resonance imaging (MRI) techniques.

5 Intended Use

The Tumark Vision is intended to attach a marker to soft tissue at the surgical site during an open or a percutaneous procedure. It is indicated for use to radiographically and radiologically mark the surgical location in breasts following an open or percutaneous procedure. It is not intended to be used with magnetic resonance imaging (MRI) techniques.

6 Technological Characteristics

Description	SOMATEX Medical Technologies --- Tumark Vision (New Device)	SOMATEX Medical Technologies --- Tumark Professional (Predicate Device)
Regulation Number	878.4300	878.4300
Class	2	2
Product Code	NEU	NEU
Design	A sterile, single use, preloaded tissue site marking system consisting of a non-absorbable nickel-titanium marker, an introducer cannula and a plastic handle	A sterile, single use, preloaded tissue site marking system consisting of a non-absorbable nickel-titanium marker, an introducer cannula and a plastic handle

Description	SOMATEX Medical Technologies --- Tumark Vision (New Device)	SOMATEX Medical Technologies --- Tumark Professional (Predicate Device)
Marker	Sphere-shaped design which is visible in ultrasound, mammography and MRI	U-shaped or X-shaped visible in ultrasound, mammography and MRI
Marker Material	Nitinol	Nitinol
Cannula Design	Sharp tip with ultrasound enhancement on the distal end, markings on the cannula and puncture function	Sharp tip with ultrasound enhancement on the distal end, markings on the cannula and puncture function
Cannula length [mm]	100 / 120	100 / 120
Cannula Diameter [mm]	1.2	1.2
Gauge [G]	18	18
Cannula Material	stainless steel	stainless steel
Handle	One-handed application with safety function to prevent premature deployment of the marker	One-handed application with safety function to prevent premature deployment of the marker
Handle Material	stainless steel and plastic	stainless steel and plastic
Sterilization Method	Ethylene oxide	Ethylene oxide

7 Design Control Activities

A risk analysis was performed to identify new risk based on the device modification. Risks are mitigated as far as possible. All verification and validation activities identified as necessary were performed by designated individuals and results demonstrate that predetermined acceptance criteria were met. The manufacturing facility fulfills design procedure requirements.

8 Substantial Equivalence Summary / Conclusion

In summary, the proposed changes do not raise any new questions regarding safety and effectiveness of the Tumark Vision. The Tumark Vision is substantially equivalent to the predicate device Tumark Professional.