February 18, 2021

SOMATEX Medical Technologies GmbH
David Vasmer
Regulatory Affairs Manager
Hohenzollerndamm 150/151
Berlin, Berlin 14199
Germany

Re: K201863
Trade/Device Name: Tumark Vision, Tumark Professional, Tumark Q, Tumark Professional Q-Shape
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable Clip
Regulatory Class: Class II
Product Code: NEU
Dated: July 3, 2020
Received: July 6, 2020

Dear Dr. Vasmer:

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/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 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 https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). 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 (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Cindy Chowdhury, Ph.D., M.B.A.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K201863

Device Name
Tumark Vision, Tumark Professional, Tumark Q, Tumark Professional Q-Shape

Indications for Use *(Describe)*
The Tumark® Vision, the Tumark® Professional, the Tumark® Q and the Tumark® Professional Q-Shape are intended to attach a marker to soft breast tissue and axillary lymph nodes, following an open or a percutaneous procedure to radiographically mark the location of the surgical site. It is not indicated 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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DATE OF APPLICATION: 18.02.2021

APPLICANT:

SOMATEX Medical Technologies GmbH
Hohenzollerndamm 150/151
14199 Berlin
Germany
Tel: + 49 (0) 30 319 82 25 00
Fax: +49 (0) 30 319 82 25 99
E-Mail: info@somatex.com

CONTACT PERSON:

David Vasmer, PhD
Regulatory Affairs Manager
Tel.: +49 (0) 30 319 82 25-49
E-Mail: D.Vasmer@somatex.com

1 Device Name

Trade Name:	*Tumark Vision* *Tumark Professional* *Tumark Q* *Tumark Professional Q-Shape*
Common Name:	*Tissue Site Marking System*
Device Classification Name:	*Marker, Radiographic, Implantable*

2 Classification / Product Code

The subjected devices 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

New Device	Predicate Device	Reference Device	510(k) Number	510(k) Holder
Tumark Vision Tumark Professional Tumark Q Tumark Professional Q-Shape	Tumark Professional	---	K073095	SOMATEX Medical Technologies GmbH
	---	Tumark Vision	K180443	SOMATEX Medical Technologies GmbH
	---	UltraCor Twirl Breast Tissue Marker	K180061	Bard Peripheral Vascular, Inc.

4 Device Description

4.1 Tumark Vision

The Tumark® Vision is a sterile product for single use only and consists of a non-absorbable nickeltitanium clip marker, an introducer cannula and a plastic handle. When new and unopened, the clip marker is contained within the cannula. The cannula tip is bevelled to help insertion, has markings 1 cm apart for measuring the depth of penetration, and a textured surface behind the cannula tip. The handle is equipped with a slide button which allows one handed placement of the marker by pressing it forward. A safety catch system prevents the slide button from inadvertently moving forward and therefore prevents premature deployment of the marker. The clip marker has a spherical shape. The symbol of the clip marker shape is depicted on the handle.

4.2 Tumark Professional

The Tumark® Professional is a sterile product for single use only and consists of a non-absorbable nickel-titanium clip marker, an introducer cannula, and a plastic handle. When new and unopened, the clip marker is contained within the cannula. The cannula tip is bevelled to help insertion, has markings 1 cm apart for measuring the depth of penetration, and a textured surface behind the cannula tip. The handle is equipped with a slide button which allows one handed placement of the marker by pressing it forward. A safety catch system prevents the slide button from inadvertently moving forward and therefore prevents premature deployment of the marker. The clip marker has a U-shape. The symbol of the clip marker shape is depicted on the handle.

4.3 Tumark Q

The Tumark® Q is a sterile product for single use only and consists of a non-absorbable nickel-titanium clip marker, an introducer cannula and a plastic handle. When new and unopened, the clip marker is contained within the

cannula. The cannula tip is bevelled to help insertion, has markings 1 cm apart for measuring the depth of penetration, and a textured surface behind the cannula tip. The clip marker can be placed using one hand by pushing the slide button on the plastic handle forward once the fixing clip has been removed. A safety catch system prevents the slide button from inadvertently moving forward and therefore prevents premature deployment of the clip marker. The clip marker has a Q-shape.

4.4 Tumark Professional Q Shape

The Tumark® Professional Q Shape is a sterile product for single use only and consists of a non-absorbable nickeltitanium clip marker, an introducer cannula and a plastic handle. When new and unopened, the clip marker is contained within the cannula. The cannula tip is bevelled to help insertion, has markings 1 cm apart for measuring the depth of penetration, and a textured surface behind the cannula tip. The handle is equipped with a slide button which allows one handed placement of the marker by pressing it forward. A safety catch system prevents the slide button from inadvertently moving forward and therefore prevents premature deployment of the marker. The clip markers for the Tumark® Professional are Q-shaped. The symbol of the clip marker shape is depicted on the handle.

5 Indication for Use

The Tumark® Vision, the Tumark® Professional, the Tumark® Q and the Tumark® Professional Q-Shape are intended to attach a marker to soft breast tissue and axillary lymph nodes, following an open or a percutaneous procedure to radiographically mark the location of the surgical site. It is not indicated to be used with magnetic resonance imaging (MRI) techniques.

6 Duration of Use

The clip marker is a permanent implant (> 30 days).

7 Technological Characteristics

The technological characteristics of Tumark® Vision, Tumark® Professional, Tumark® Q and Tumark® Professional Q-Shape are the same as the technological characteristics of the predicate device.

7.1 Device Characteristics Table

Company	**SOMATEX Medical Technologies GmbH --- Tumark Vision, Tumark Professional Tumark Q Tumark Professional Q-Shape (New Device)**	**SOMATEX Medical Technologies GmbH --- Tumark Professional (Predicate Device)**	**SOMATEX Medical Technologies GmbH --- Tumark Vision (Reference Device)**	**Bard Peripheral Vascular, Inc. --- UltraCor Twirl Breast Tissue Marker (Reference Device)**	**Result**
Device Name	Tumark Vision, Tumark Professional Tumark Q Tumark Professional Q-Shape	Tumark Professional	Tumark Vision	UltraCor Twirl Breast Tissue Marker	---
Regulation Number	878.4300	878.4300	878.4300	878.4300	Substantially Equivalent
Class	2	2	2	2	Substantially Equivalent
Code	NEU	NEU	NEU	NEU	Substantially Equivalent
510(k) number	---	K073095	K180443	K180061	---

Company	SOMATEX Medical Technologies GmbH --- Tumark Vision, Tumark Professional Tumark Q Tumark Professional Q-Shape (New Device)	SOMATEX Medical Technologies GmbH --- Tumark Professional (Predicate Device)	SOMATEX Medical Technologies GmbH --- Tumark Vision (Reference Device)	Bard Peripheral Vascular, Inc. --- UltraCor Twirl Breast Tissue Marker (Reference Device)	Result
Indication for Use	The Tumark® Vision, the Tumark® Professional, the Tumark® Q and the Tumark® Professional Q-Shape are intended to attach a marker to soft breast tissue and axillary lymph nodes, following an open or a percutaneous procedure to radiographically mark the location of the surgical site. It is not indicated to be used with magnetic resonance imaging (MRI) techniques.	The Tumark Professional 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.	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.	The UltraCor® Twirl® Breast Tissue Marker is intended for use to attach to soft breast tissue, including axillary lymph nodes, to radiographically mark the location of the biopsy procedure.	Substantially Equivalent
Design	Sterile, single use, preloaded tissue site marking systems consisting of a non-absorbable nickel-titanium marker, a cannula and a plastic handheld applier with deployment mechanism.	Sterile, single use, preloaded tissue site marking systems consisting of a non-absorbable nickel-titanium marker, a cannula and a plastic handheld applier with deployment mechanism.	Sterile, single use, preloaded tissue site marking systems consisting of a non-absorbable nickel-titanium marker, a cannula and a plastic handheld applier with deployment mechanism.	Sterile, single use, preloaded tissue site marking systems consisting of a non-absorbable nickel-titanium marker, a cannula and a plastic handheld applier with deployment mechanism.	Substantially Equivalent
Marker Design	Sphere-shaped; U-shaped, Q-shaped	U-shaped	Sphere-shaped	Ring-shaped	Substantially Equivalent
Marker Material	Nitinol	Nitinol	Nitinol	Nitinol	Substantially Equivalent
Cannula Design	Sharp tip, markings on the cannula and puncture function	Sharp tip, markings on the cannula and puncture function	Sharp tip, markings on the cannula and puncture function	Sharp tip, markings on the cannula and puncture function	Substantially Equivalent
Cannula length [mm]	70 / 100 / 120 / 150	70 / 100 / 120	100 / 120	100	Substantially Equivalent
Gauge [G]	18	18	18	17	Substantially Equivalent
Cannula Material	stainless steel	stainless steel	stainless steel	stainless steel	Substantially Equivalent
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	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	Substantially Equivalent
Handle Material	stainless steel plastic material	stainless steel plastic material	stainless steel plastic material	plastic material	Substantially Equivalent

7.2 Summary of Technological Characteristics

The proposed devices are similar in terms of design, indication for use and have similar technological characteristics as the predicate device and reference devices. It can be stated, that Tumark Vision, Tumark Professional, Tumark Q

and Tumark Professional Q-Shape are considered substantially equivalent to the predicate device/reference devices.

8 Performance Data

To demonstrate that Tumark Vision, Tumark Professional, Tumark Q and Tumark Professional Q-Shape are as safe and effective as the predicate and reference devices, their technological characteristics and performance criteria were evaluated. The new devices were evaluated in bench and in vitro testing. Specific aspects included:

8.1 Biocompatibility

The components and manufacturing processes of the subjected devices are similar to the predicate device Tumark Professional (K073095) and the reference device Tumark Vision (K180443). The devices are made from standard materials. EO residual values are far below the acceptable limits. In addition, cytotoxicity testing and the toxicological review confirmed the absence of toxic leachables and contaminants. Therefore, the requirements of ISO 10993-1 are met and further testing is deemed not necessary.

8.2 Sterilization and Shelf Life

The devices are delivered in sterile state. All acceptance criteria are met during the sterility testing. Furthermore, the defined shelf-life could be proven based on packaging and device testing after real-time ageing. All defined acceptance criteria were met during shelf life testing.

8.3 Bench Testing

Bench testing was performed to validate the device design. Specific aspects include:

Aspect	Test Method	Results
Device Function	Confirm that the marker can be placed in the target area	U-, Q- and Vision markers could be deployed. The device performs as intended. All acceptance criteria are met.
Device Performance	Confirm that the clip marker and cannula are recognized	Clip markers and cannulas are recognized in ultrasound, mammography and MR imaging. All acceptance criteria are met.
Device Stability during transport	Drop tests	Devices were not damaged. All acceptance criteria are met.

All acceptance criteria were met during the bench testing. The devices perform as intended and are as safe and as effective as the predicate device.

8.4 Clinical Analysis

A literature review was performed to clinically support the use of the markers inside axillary lymph nodes. This literature review confirms the defined indication for use. Furthermore, physician statements were obtained to support the indication for use.

9 Substantial Equivalence Summary / Conclusion

Based on available 510(k) information herein provided, Tumark Vision, Tumark Professional, Tumark Q and Tumark Professional Q-Shape are considered substantially equivalent to the predicate device/reference devices in terms of intended use, technology and performance specifications. There are no differences between the devices which may raise new issues concerning safety or effectiveness.