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MADE IN GERMANY

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FEB 17 2010

# 510(k) SUMMARY

## Tumark® Professional / MRI Tumark® Professional

**Submitter:**

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14513 Teltow
Germany
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**Official Correspondent:**

Susanne Raab

Regulatory Affairs Consultant
1480 Cambridge Street
Cambridge, MA 02139
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**Trade Name:** Tumark® Professional / MRI Tumark® Professional

**Common Name:** Tissue Site Marking System

**Classification Name:** Radiographic Implantable Marker, 21 C.F.R. 878.4300

**Regulatory Class:** II

**Product Code:** NEU

**Device Description:** The Tumark® Professional and MRI Tumark® Professional 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 Tumark® Professional is not

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indicated to be used in Magnetic Resonance Imaging (MRI) procedures. The MRI Tumark® Professional is MRI Safe and indicated to be used during MRI procedures. The introducer cannula which will be available in stainless steel (Tumark® Professional) or cobalt-chrome alloy (MRI Tumark® Professional) for use with magnetic resonance imaging techniques is designed with 1 cm depth marks, a beveled tip and an ultrasound enhancement on the distal end. The cannulas will be available in different lengths. The handle is equipped with a slide-button which allows for a one handed placement. A safety catch system prevents the slide-button from inadvertently moving forward and therefore prevents a premature deployment of the marker. The Tumark® Professional will be available with a U-shaped or X-shaped marker. The MRI Tumark® Professional will only be available with a U-shaped marker.

**Intended Use:**

The Tumark® Professional and MRI Tumark® Professional are intended to attach a marker to soft tissue at the surgical site during an open or a percutaneous procedure.

The devices are indicated for use to radiographically and radiologically mark the surgical location in breasts following an open or percutaneous procedure. Only the MRI Tumark® Professional is indicated to be used in Magnetic Resonance Imaging (MRI) procedures.

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**Substantial Equivalence:**

The Tumark® Professional and MRI Tumark® Professional are substantial equivalent to the Tumark® Professional, also manufactured by Somatex Medical Technologies GmbH, that has been cleared by FDA on March 19, 2008 (K073095), the ClipLoc Soft Tissue marker, manufactured by MRI Devices Corporation (K033447) and the UltraClip Tissue Marker, manufactured by Inrad Inc. The Tumark® Professional and MRI Tumark® Professional and each of their predicate devices are intended to attach a marker to soft tissue at the surgical site during an open or a percutaneous procedure. All devices are indicated for use to radiographically and radiologically mark the surgical location in breasts following an open or percutaneous procedure.

In addition, both the proposed devices and the predicate devices are identical or similar in technology, design and material. In particular, the proposed devices and the predicate devices consist of the same primary components and the component materials of the proposed devices and the predicate devices are substantially equivalent. Furthermore, biocompatibility, sterility and packaging testing of the proposed devices demonstrate the safety and effectiveness of the system.

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Based on the same intended use and the similiarities in technology, design and materials the Tumark® Professional and MRI Tumark® Professional are substantially equivalent to their predicate devices. The minor technological differences between the proposed devices and the predicate devices do not raise new questions of safety and effectiveness.

**Date Prepared:** January 18, 2010

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

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

FEB 17 2010

Somatex Medical Technologies, GmbH
% Ms. Susanne Raab
1480 Cambridge Street
Cambridge Massachusetts 02139

Re: K093064
Trade/Device Name: Tumark® Professional/MRI Tumark® Professional
Regulation Number: 21 CFR 878.4300
Regulation Name: Implantable clip
Regulatory Class: II
Product Code: NEU
Dated: January 20, 2010
Received: January 25, 2010

Dear Ms. Raab:

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.

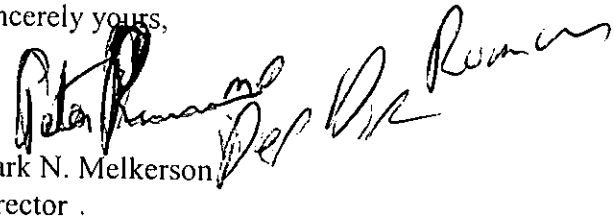
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further 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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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,



Mark N. Melkerson
Director
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

# Indication for Use

510(k) Number (if known): _____

Device Name: Tumark® Professional / MRI Tumark® Professional

Indications for Use:

The Tumark® Professional and MRI Tumark® Professional are intended to attach a marker to soft tissue at the surgical site during an open or a percutaneous procedure.

The devices are indicated for use to radiographically and radiologically mark the surgical location in breasts following an open or percutaneous procedure. Only the MRI Tumark® Professional is indicated to be used in Magnetic Resonance Imaging (MRI) procedures.

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 OF NEEDED)

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Concurrence of CDRH, Office of Device Evaluation (ODE)

David Krause for MKM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K093064