DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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April 11, 2017

Summit Medical, Inc.
Nicole Dove
QA/RA Manager
815 Northwest Parkway, Suite 100
St. Paul, Minnesota 55121

Re: K162046
Trade/Device Name: MINNE TIES MMF Suture System
Regulation Number: 21 CFR 872.4600
Regulation Name: Intraoral Ligature And Wire Lock
Regulatory Class: Class II
Product Code: DYX
Dated: March 16, 2017
Received: March 17, 2017

Dear Nicole Dove:

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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

Indications for Use

510(k) Number *(if known)*
K162046

Device Name
MINNE TIES MMF Suture System

Indications for Use *(Describe)*
The MINNE TIES MMF Suture System is an adjustable flexible plastic band that wraps between and around a tooth to create an anchorage point for maxilla-mandibular fixation and immobilization. MINNE TIES MMF Suture System is suitable for:

- Pre-operative fixation
- Per-operative fixation
- Short-term (up to 3 weeks) fixation for minimally displaced fractures
- Splintage post jaw dislocation

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
K162046/S001

Following is a summary of 510(k) safety and effectiveness information in accordance with 21 CFR 807.92

Date Prepared:	March 16, 2017
Applicant:	Summit Medical, Inc. 815 Northwest Parkway, Suite 100 St. Paul, MN 55121 | USA
Official Correspondent:	Nicole Dove QA/RA Manager Tel: (651) 789-3921 / Fax: (651) 789-3961 ndove@summitmedicalusa.com
Subject Device	
Trade/Device Name:	MINNE TIES™ MMF Suture System
Common or Usual Name:	Intraoral ligature and wire lock
Regulation Number:	21 CFR 872.4600
Regulation Name:	Intraoral Ligature and Wire Lock
Regulatory Class:	Class II
Product Code:	DYX
Indications for Use	The MINNE TIES™ MMF Suture System is an adjustable flexible plastic band that wraps between and around a tooth to create an anchorage point for maxilla-mandibular fixation and immobilization. MINNE TIES™ MMF Suture System is suitable for: - Pre-operative fixation - Per-operative fixation - Short-term (up to 3 weeks) fixation for minimally displaced fractures - Splintage post jaw dislocation
Device Description	The MINNE TIES™ MMF Suture System contains: - Four (4) 1.0mm sized sutures - Seven (7) 0.7mm sized sutures - One (1) 0.5mm Sized suture and are used to establish maxilla-mandibular fixation (MMF) and immobilization by applying independently balanced series of sutures bilaterally between and/or around the teeth in the interdental space (i.e. triangular apical embrasure). The sutures provide a stabilizing occlusive force allowing for short term (up to 3 weeks) fixation for minimally displaced fractures, for pre-operative and per-operative fixation and

	splintage post jaw dislocation. An Introducer is used to advance sutures between and/or around the teeth. A cheek retractor is included with the system to organize the ties during the procedure. The MINNE TIES™ MMF Sutures are made of polypropylene, polyester and stainless steel. The cheek retractor is made of polypropylene.

Predicate Device	
Trade/Device Name/510(k)	Rapid IMF™ - K030605

Comparison of Subject Device to Predicate Device	MINNE TIES™ MMF Suture System – K162046/S001 (under review)	Predicate Device: Rapid IMF™ – K030605
Indications for Use	The MINNE TIES™ MMF Suture System is an adjustable flexible plastic band that wraps between and around a tooth to create an anchorage point for maxilla-mandibular fixation and immobilization. MINNE TIES™ MMF Suture System is suitable for: - Pre-operative fixation - Per-operative fixation - Short-term (up to 3 weeks) fixation for minimally displaced fractures - Splintage post jaw dislocation	The Rapid IMF™ is an adjustable flexible plastic band that wraps around a tooth to create an anchorage point for maxilla-mandibular fixation and immobilization (similar to an orthodontic band). Rapid IMF™ is suitable for: - Pre-operative fixation - Per-operative fixation - Short-term (up to 3 weeks) fixation for minimally displaced fractures - Splintage post jaw dislocation
Anatomical Site	Oral cavity	Oral cavity

Technological Characteristics/Performance Comparison of Subject Device to Predicate Device	MINNE TIES™ MMF Suture System – K162046/S001 (under review)	Predicate Device: Rapid IMF™ – K030605
Materials	Plastic (polypropylene, polyester)	Plastic (nylon, elastic) and stainless

	and stainless steel	steel
Performance - **Mechanical safety**	Blunt device, less potential damage to oral mucosa	Blunt device, less potential damage to oral mucosa
- **Human factors**	Less risk of glove puncture as blunt device	Less risk of glove puncture as blunt device
- **Biocompatibility**	Biocompatible with respect to tests carried out	Biocompatible; has history of clinical use
- **Time Used**	Single Use Only, up to 3 weeks	Single Use Only, up to 3 weeks
Sterility	Terminal sterilization by ethylene oxide, sterility assurance level 10^{-6}	Terminal sterilization by ethylene oxide, sterility assurance level 10^{-6}
Clinical testing	Clinical data is not required.	Clinical data was not required for the predicate device.
Non-Clinical Testing	The MINNE TIES™ MMF Suture System proved to be successful in all the non-clinical tests conducted. The non-clinical tests conducted included the tests listed below and demonstrated substantial equivalence of the subject device. - Mechanical stability of construct (performance, tensile strength) - Biocompatibility - Corrosion resistance - System handling, End-user (cadaver test) - Packaging - Shelf Life - Sterilization, Ethylene Oxide Residuals, Bioburden	The Rapid IMF™ conducted the following non-clinical tests: - Tensile Strength Test - Biocompatibility - Bioburden - Ethylene Oxide Residuals
Non-Clinical Testing Summary	The following Non-Clinical Testing was conducted using current standards and guidance and demonstrated substantial equivalence of the subject device. - Biocompatibility per ISO 10993-1: Cytotoxicity per ISO 10993-5, Sensitization per ISO 10993-10 and Irritation per ISO 10993-10 - Sterile barrier system testing per Distribution Cycle ASTM D4169, Visual Inspection ASTM F1886-09, Gross Leak Detection ASTM	

	F2096-11, Seal Strength ASTM F88-09 and Accelerated Aging ASTM F1980-07 - Ethylene Oxide Sterilization validation per ANI/AAMI/ISO 11135-1:2007 - Mechanical stability of construct (fatigue, tensile, strength, floss-out) - Corrosion resistance - System handling, End-user (cadaver test)
Conclusion:	In summary, the MINNE TIES™ MMF Suture System has the following similarities to the predicate device which has previously received 510(k) clearance: - Has the same indications for use - Has the same intended use - Has the same target population - Has the same implant duration - Used in the same anatomical site - Uses similar technological characteristics - Uses similar biocompatible materials - Has the same sterility assurance level The differences in technological characteristics between the subject device and predicate device are mitigated by the following bench tests: - Tensile strength - Fatigue strength - Floss out - Human Factors Therefore, the MINNE TIES™ MMF Suture System is substantially equivalent to the predicate device.