Teknimed
% Barry E Sands
President and Founder
RQMIS, Inc.
110 Haverhill Rd., Suite 524
Amesbury, Massachusetts 01913

Re: K230394
Trade/Device Name: Euroscrew® NG; Euroscrew® TCP NG
Regulation Number: 21 CFR 888.3030
Regulation Name: Single/Multiple Component Metallic Bone Fixation Appliances And Accessories
Regulatory Class: Class II
Product Code: MAI,
Dated: February 14, 2023
Received: February 14, 2023

Dear Barry Sands:

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,

Yu-chieh Chiu -S

Digitally signed by Yu-chieh Chiu -S
Date: 2023.05.12 13:43:23 -04'00'

Yu-Chieh Chiu, Ph.D.
Acting Assistant Director
DHT6C: Division of Restorative, Repair and Trauma Devices
OHT6: Office of Orthopedic 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)*
K230394

Device Name
EUROSCREW® NG
EUROSCREW® TCP NG

Indications for Use *(Describe)*
EUROSCREW® NG and EUROSCREW® NG TCP screws are indicated in knee anterior cruciate ligament reconstruction in ligamentoplasty procedures.

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

Submitter information

Date Prepared per 21 CFR 807.92(a)(1)	May 11, 2023
Applicant/Manufacturer	Teknimed 11-12 rue Apollo Z.I. Montredon L'Union 31240, France
Primary Contact	Barry Sands President and Founder, RQMIS Phone: (978) 358-7307 Email: regulatorysubmissions@rqmis.com

Device information

Trade Name of Subject Device	EUROSCREW® NG & EUROSCREW® TCP NG
Common Name	Fastener, Fixation, Biodegradable, Soft Tissue
Device class	Class II
Product Code	MAI
Regulation Number	888.3030 Single/multiple component metallic bone Fixation appliances and accessories
Predicate Device:	LIGAFIX Interference Screw (K122228)

Device Description

Teknimed's EUROSCREW® NG and EUROSCREW® TCP NG are bioabsorbable interference screws used in ligament surgery specifically designed for fixation of both bone-tendon-bone and soft tissue grafts. The screws are suitable and designed for ligamentoplasty surgical procedures specifically for knee anterior cruciate ligament reconstructions. Both are implantable screw devices in long term contact with bone and tissue grafts. Teknimed's EUROSCREW® NG and

EUROSCREW® TCP NG are implant devices that are utilized in a surgical setting with a qualified healthcare professional (i.e., surgeons).

Indications for Use

EUROSCREW® NG and EUROSCREW® TCP NG screws are indicated in knee anterior cruciate ligament reconstruction in ligamentoplasty procedures.

Intended Use

EUROSCREW® NG and EUROSCREW® TCP NG are intended for attaching ligaments or tendons to bone in orthopaedic surgical procedures.

Intended Use/Indication for Use – Comparison of the Subject Devices with Predicate Device

The subject devices, EUROSCREW® NG and TCP NG, have equivalent intended use, indications for use, material composition to the predicate device, LIGAFIX Interference Screw (K122228).

Technological Characteristics – Comparison with the Predicate Device, LIGAFIX Interference Screw (K122228)

The technological characteristics comparison demonstrated that the subject devices, EUROSCREW® NG and EUROSCREW® TCP NG, are equivalent to the previously cleared predicate device in terms of intended uses, designs, materials, and operational principles.

Basis of Substantial Equivalence

The substantial equivalence of both subject devices was determined per the FDA guidance document, "***The 510(k) program: evaluating substantial equivalence in premarket Notification [510(k)].***" Comparison with the predicate device (K122228) does not raise new questions of safety and effectiveness. The analysis of the technological characteristics, which include design, material composition and other device features, as defined in section 513(i)(1)(B) of the FD&C Act and 21 CFR 807.100(b)(2) (ii)(A), demonstrated that EUROSCREW® NG and EUROSCREW® TCP NG are substantially equivalent to the identified predicate device, LIGAFIX Interference Screw (K122228).

Sterilization

EUROSCREW® NG and TCP NG will be supplied sterile. EUROSCREW® NG and EUROSCREW® TCP NG are delivered in double sterile packaging. Both subject devices are sterilized by ethylene oxide and are provided sterile for single patient use. The sterilization validations are performed per ISO 11135-1 and ISO 10993-7 FDA recognized consensus standards. The sterilization validation demonstrated that both subject devices are effective at all points of load and achieve a sterility assurance level (SAL) of 10^{-6}.

Biocompatibility

Biocompatibility testing was performed on both Teknimed subject devices, and the test results demonstrated that EUROSCREW® NG and EUROSCREW® TCP NG are biocompatible. Biocompatibility of both devices were evaluated according to the FDA guidance document entitled, Use of International Standard ISO 10993-1, "Biological Evaluation of Medical Devices - Part 1: Evaluation and Testing within a Risk Management Process" issued on September 4, 2020. Based on this FDA guidance document, both the subject devices are considered implants which come in permanent contact (>30 days) with bone and tissue of the patient's body.

Performance Testing

Both the subject devices, EUROSCREW® NG and EUROSCREW® TCP NG, were tested for torsion, torque (insertion) and pull-out as per ASTM F 2502, and for In Vitro Degradation as per ISO 13781. The company also performed Insertion Validation and Association screwdriver-screw tests to assess screw insertion criteria. Performance test reports confirmed that the difference between the predicate (LIGAFIX Interference Screw (K122228)) and subject devices, EUROSCREW® NG and TCP NG, do not raise any new questions of safety or effectiveness. Therefore, both subject devices are substantially equivalent to the predicate device identified throughout this submission.

Table 1: Substantial Equivalence Comparison Table between EUROSCREW®NG and TCP NG (Subject Devices) with LIGAFIX® Interference Screw (K122228)

Device Characteristics	**Subject Devices**	**Predicate Device**	**Substantial Equivalence Discussion**
Products	EUROSCREW® NG and TCP NG	LIGAFIX Interference Screw (30/70)	**N/A**
Applicant	Teknimed	SBM	
510(k) Number	K230394	K122228	
Classification	Class II	Class II	**Identical**
Classification Name	888.3030 Single/multiple component metallic bone Fixation appliances and accessories	888.3030 Single/multiple component metallic bone Fixation appliances and accessories	**Identical**
Product Code	MAI	MAI	**Identical**

Indications for use	EUROSCREW® NG and EUROSCREW® TCP NG screws are indicated in knee anterior cruciate ligament reconstruction in ligamentoplasty procedures.	LIGAFIX/ComposiTCP is a cannulated; sterile, single use, resorbable interference bone screw made of a mixture of tri calcium phosphate (beta-TCP) and Poly Lactic Acid (PLA) designed for' the interference fixation of grafts in anterior cruciate ligament reconstruction.	**Equivalent** Both Subject devices and the predicate device have equivalent Indications for use.
Sterile	Ethylene Oxide (EtO)	Unknown	**Equivalent** Both Subject devices meet **ISO 10993-7** specification. The Sterilization tests' results for both subject devices passed, and reports are attached in the original 510(K) body.
Material	Euroscrew NG: Poly Lactic Acid (PLA) & Euroscrew TCP NG Tri calcium phosphate (beta-TCP) and Poly Lactic Acid (PLA)	Tri calcium phosphate (beta-TCP) and Poly Lactic Acid (PLA)	**Equivalent** Both subject devices and the predicate devices have equivalent materials. Both Subject devices and the predicate devices meet **ASTM F2502** specifications.
Available sizes	Ø 6 mm L 20 mm Ø 7 mm L 24 mm Ø 8 mm L 24 mm Ø 9 mm L 24 mm Ø 7 mm L 30 mm Ø 8 mm L 30 mm Ø 9 mm L 30 mm Ø 10 mm L 30 mm Ø 11 mm L 35 mm	Flat head Ø 10 mm - L 30 mm Ø 10 mm - L 35 mm Ø 11 mm - L 30 mm Ø 11 mm - L 35 mm Round head Ø 6 mm - L 20 mm Ø 7 mm - L 20 mm Ø 7 mm - L 25 mm Ø 7 mm - L 30 mm Ø 8 mm - L 20 mm Ø 8 mm - L 25 mm Ø 8 mm - L 30 mm	**Equivalent** Size range is equivalent to the Predicate device.

		Ø 8 mm - L 35 mm Ø 9 mm - L 20 mm Ø 9 mm - L 25 mm Ø 9 mm - L 30 mm Ø 9 mm - L 35 mm Ø 10 mm - L 25 mm Ø 10 mm - L 30 mm Ø 10 mm - L 33 mm Ø 10 mm - L 35 mm	
How Supplied	Resorbable interference bone screw, Single use only	Resorbable interference bone screw, Single use only	**Identical**
Biocompatible	ISO 10993-1	Biocompatible	**Equivalent** Both Subject and predicate devices testing protocols/reports for the screws meet **ISO 10993** specification. All tests' results for the subject device passed and reports are attached in the original 510(K) body

Substantial Equivalence Conclusion

EUROSCREW® NG and EUROSCREW® TCP NG have equivalent intended use, material comparison, design, operational principle and equivalent technological characteristics as the predicate device (K122228). The non-clinical performance test reports support the safety, effectiveness and performance of the subject devices and demonstrate that any difference in technological characteristics and material composition do not rase any new questions of safety and effectiveness. Therefore, EUROSCREW® NG and EUROSCREW® TCP NG are substantially equivalent to the identified predicate device, LIGAFIX Interference Screw (K122228).