March 8, 2022

TendoNova Corporation
% Paul Dryden
Consultant
ProMedic Consulting LLC
131 Bay Point Dr NE
Saint Petersburg, Florida 33704

Re: K212049
Trade/Device Name: Oclet TDS 1000
Regulatory Class: Unclassified
Product Code: LFL
Dated: February 4, 2022
Received: February 7, 2022

Dear Paul Dryden:

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,

Long Chen, Ph.D.
Assistant Director
DHT4A: Division of General 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)*
K212049

Device Name

Ocelot TDS 1000

Indications for Use *(Describe)*

The Ocelot TDS 1000 is indicated for use during surgical procedures when fragmentation or debridement of soft tissue is desired.

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.

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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Date Prepared: 8-Mar-22

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Official Contact: Mark Samuels - CEO

Submission Correspondent: Paul Dryden
ProMedic, LLC
131 Bay Point Dr NE
St. Petersburg, FL 33704

Proprietary or Trade Name: Ocelot TDS 1000

Common/Usual Name: Instrument, Ultrasonic Surgical
Classification CFR: Unclassified
Classification Code: LFL
Classification Name: Instrument, Ultrasonic Surgical
Class: Unclassified

Predicate Device: K153299, Tenex Tx1
Common/Usual Name: Instrument, Ultrasonic Surgical
Classification CFR: Unclassified
Classification Code: LFL
Classification Name: Instrument, Ultrasonic Surgical
Class: Unclassified

Device Description:
The Ocelot TDS 1000 is a portable, handheld battery-powered device that consists of a Reusable Drive Unit (RDU), a charging station for the RDU, a sterile Disposable Unit (DU) that houses the cutting tool assembly, and an optional application that displays real-time operating data. The Ocelot TDS 1000 is comprised of a unit that mechanically interacts with tissue and an app that provides real-time device operating data. A battery charging unit is provided to recharge the battery.

Indications for Use:
The Ocelot TDS 1000 is indicated for use during procedures when fragmentation or debridement of soft tissue is desired.

Technological Characteristics Comparison:

	Subject Device: TendoNova Ocelot Treatment Delivery System 1000 (TDS)	**Predicate Device** Tenex Health TX System (K153299)	**COMPARISON**
User Interface	Display Unit (Tablet)	Display Unit (Console)	Similar
User Interface	Handheld Tip (Battery Powered)	Handheld Tip (Cord)	Similar
Technology	Mechanically fragments and debrides tissue at the target site	Ultrasonically fragments and debrides tissue at the target site	The procedure is similar while the frequency is different.
Controls	Adjustable Cutting Speed	Adjustable Cutting Power	Similar
Power delivery	Continuous	Continuous or Pulsed	Similar
Irrigation	Manual with Syringe (with optional luer)	Automatic with pump	Similar
Aspiration	Manual with Syringe (with optional Luer)	User selectable with Pump	Similar
Activation	Manual with Push button	Manual with foot switch	Similar
Tissue Interface Size	18 Gauge Cannula	18 Gauge Cannula	Identical
Tissue Cutting	Vibrating Cutting tip (mechanical)	Vibrating Cutting tip (Ultrasonic)	Similar
Handpiece	Disposable	Disposable	Similar
Power	110 V AC mains to wireless battery charger	110 V AC Mains to wired cord	Similar

	Subject Device: TendoNova Ocelot Treatment Delivery System 1000 (TDS)	**Predicate Device** Tenex Health TX System (K153299)	**COMPARISON**
Procedure time	Measures Cutting time	Measures Cutting time	Identical
Indications for Use	The Ocelot TDS 1000 is indicated for use during procedures when fragmentation or debridement of soft tissue is desired.	The Tenex Health TX System is indicated for use in surgical procedures where fragmentation, emulsification and aspiration of soft tissue are desirable, including General Surgery, Orthopedic Surgery, Laparoscopic Surgery and Plastic and Reconstructive Surgery.	The indications for use of the subject device fall within the indication for use of the predicate device
Components	Disposable Handheld cutting tip	Disposable Handheld Cutting Tip	Similar
	Tablet with Display (optional)	Console with Display	Similar
	Optional Manual Irrigation and Aspiration	Inflatable cuff and pump for irrigation and aspiration	Similar
	Disposable Cutting Tip	Disposable Cutting tip	Similar
	Reusable Driver	Reusable Driver Console	Similar
Mechanism of Action	Oscillating Needle 9 Hz to 27 Hz	Oscillating Needle – 25 kHz to 28 kHz	While the subject device's mechanism of action is different from the predicate the subject device shares a similar intended use and has similar technological characteristics as the predicate device.

	Subject Device: TendoNova Ocelot Treatment Delivery System 1000 (TDS)	**Predicate Device** Tenex Health TX System (K153299)	**COMPARISON**
Specifications	**MicroTip needle:** **Length:** 30 mm to 84 mm **Outer Diameter:** 18-gauge **Inner Needle:** 22-gauge **Tip Frequency**: 9 Hz to 25 Hz **Power source:** 100-240V, 50/60 Hz **Cutting Tip Needle:** **Needle Lengths:** 30mm, 60mm, 84mm **Cutting travel distance:** 2.5 +/- 0.5mm	**MicroTip needle:** **Length:** 25.4 mm to 43.2mm **Outer Diameter:** 18-gauge **Inner Needle:** N/A **Tip Frequency**: 25 kHz to 28 kHz **Power source:** 100-240V, 50/60 Hz **Cutting Tip Needle:** **Needle Lengths:** 25.4mm, 58.4mm **Cutting travel distance:** none	Similar
User Interface	Off-the-shelf Tablet has color LCD touch screen with graphical user interface and Reusable has LED display for power and pairing information	Color LCD touch screen with graphical user interface for selection of required settings.	Similar

Difference Between Subject and Predicate

While both are handheld devices that fragment or debride soft tissue, there are some technological differences between the subject device and the predicate device (K153299). The key technological difference is that the subject device mechanically oscillates the cutting tip to fragment or debride tissue at the target site whereas the predicate device (K153299) ultrasonically oscillates the cutting tip to fragment or debride tissue. The predicate device (K153299) allows for irrigation of the target site to, for example, cool the ultrasonic tip. The subject device provides for optional manual irrigation and aspiration using a syringe attached to the cannula. The Ocelot oscillates between 9 Hz and 25 Hz which is much lower than the predicate. The Ocelot does not require irrigation for cooling.

Substantial Equivalence Discussion

The subject device and predicate device (K153299) each are intended for fragmentation or debridement of soft tissue.

The subject device and the predicate (K153299) are comprised of similar device components. The subject device and predicate device both consist of a disposable handheld piece with an 18-gauge cannula. While the subject device's handheld piece is battery powered and the predicate device's handheld piece is connected via cord to the console, both devices use a needle to access a site and then using the action of the needle, fragment tissue at the target site. The subject device's display unit showcases procedure time (however control is more conveniently located on the handpiece) and the display unit for the predicate device (K153299) identically showcases procedure time and provides control over the user functions. Although, subject device's display unit has slightly different functions than that of the predicate device, both display units are providing sufficient information to the user. Both devices are adjustable as to cutting frequency. The subject device and predicate device share similar dimensions of the cutting tip needle. Both device cutting tip needles are manufactured from 304 Stainless Steel (SS) and are 18-gauge. The subject device has cutting tip needle lengths which are similar to the lengths of the predicate device. The subject device's handheld piece can adjust the cutting speed and measure the cutting time, this is the same functionality as the predicate device's adjustment of cutting power and measurement of cutting time. While the frequency at which the of the subject device's cutting tip needle oscillates is different to the predicate device's cutting tip needle, both devices use a rapidly moving cutting tip needle to fragment the soft tissue at the target site. The subject device's cutting tip needle mechanically oscillates while the predicate device ultrasonically oscillates, however, both the subject and predicate device cutting tip needle interacts with the tissue at the target site.

The subject device at user preference can manually irrigate and aspirate the target site via a syringe while the predicate device irrigates and aspirates the target site with an inflation cuff and foot pedal. The devices use different methods to perform this function, both devices share similar characteristics as they perform irrigation and aspiration as needed. Comparative testing demonstrated equivalent performance.

Sterilization

The Disposable Unit is provided sterile via Ethylene Oxide (EO). Sterilization validation was performed ISO 11135:2014/Amd.1:2018 Annex E, Half cycle approach. Clinical batch release using the overkill method, as outlined in Annex E of ISO 11135 that is intended to achieve a SAL of 10-6.

Biocompatibility

The subject device is considered as Surface Contact, breached tissue and of Limited Duration (< 24 hours).The patient contacting material is 304 stainless steel and complies with ISO 9626: Stainless steel needle tubing for the manufacture of medical devices.

Standards

Testing was performed referencing these standards:

- ISO 9626: Stainless steel needle tubing for the manufacture of medical devices specifies materials made to ISO 15510 standard
- AAMI ANSI ES 60601-1: 2005 + A1: 2012 Medical electrical equipment - Part 1: General requirements for basic safety and essential performance
- IEC 60601-1-2: 2014 Collateral standard: Electromagnetic Disturbances - Requirements and Tests ASTM 4169D Schedule F – Loose Load Vibration and Schedule E – Vehicle Vibration
- Coexistence standard testing as per K212049, i.e., ANSI IEEE C63.27-2017.

Performance Testing

Testing was performed as follows:

- Software verification and validation
- Bench testing
    - Design Verification - Push and pull strength; cutting speed; drop test, functional testing.
    - Bovine Muscle Tissue – Fragmentation or debridement comparison testing
- Comparative Cadaver testing
        - Safety – Tendon tissue damage comparison testing.
        - Effectiveness - Tendon tissue fragmentation and debridement comparison testing.
- Comparative simulated irrigation and aspiration
    - Safety - Irrigation and aspiration of simulated calcific tendon material comparison testing
    - Effectiveness - Irrigation and aspiration of simulated calcific tendon material comparison testing

Substantial Equivalence Conclusion

The subject device and predicate device (K153299) technological characteristics are similar. The subject device's mechanism of action is similar to the predicate device (K153299), that is both devices debride or fragment soft tissue. The subject device has demonstrated substantially equivalence in performance, safety and effectiveness compared to the predicate device for the fragmentation or debridement of soft tissue.