September 15, 2022

UroCure LLC
Denise Lenz
Regulatory Consultant
Libra Medical, Inc.
8401 73rd Avenue North, Suite 63
Brooklyn Park, MN 55428

Re: K222468
Trade/Device Name: ArcTO Transobturator Sling System
Regulation Number: 21 CFR§ 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: II
Product Code: OTN
Dated: August 15, 2022
Received: August 16, 2022

Dear Denise Lenz:

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,

for
Jessica K. Nguyen, Ph.D.
Assistant Director
DHT3B: Division of Reproductive,
Gynecology and Urology Devices
OHT3: Office of GastroRenal, ObGyn,
General Hospital and Urology 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)*
K222468

Device Name
ArcTO Transobturator Sling System

Indications for Use *(Describe)*
The polypropylene sling is indicated to be placed mid-urethra for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

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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7 510(K) SUMMARY

7.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: Aug 15, 2022

7.2 SUBMITTER INFORMATION

Submitter

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7.3 CONTACT INFORMATION

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7.4 DEVICE INFORMATION

Trade Name	ArcTO Transobturator Sling System
Common Name	Urinary sling
Classification Name	Surgical Mesh
Classification Regulation	878.3300
Class	II
Panel	Gastroenterology/Urology
Product Code	OTN
Prior Regulatory Submissions for Device	None

7.5 510(K) TYPE AND REASON FOR SUBMISSION

This 510(k) is a Special 510(k) and is submitted to obtain marketing clearance for the ArcTO Transobturator Sling System, a modification to the delivery device for the predicate ArcTV

Transvaginal Sling. The implantable portion of the device is identical to the predicate (ArcTV), with the delivery tool being the only difference from the predicate, ArcTV.

7.6 PREDICATE DEVICE

The predicate is ArcTV Transvaginal Sling System (K183134).

7.7 DEVICE DESCRIPTION

The ArcTO Transobturator Sling System consists of the following:

- 1 ArcTO Sling with bio-resorbable Suture and plastic sheath
- 2 ArcTO Handle and Needle Delivery Assemblies

The Handle and Needle delivery assembly is a sterile, single-use system, consisting of two helical, stainless-steel Needles with attached Handles. The tip portion of each delivery Needle is designed to allow for passage through tissue. The Needles are a tool and together with the Sling Connectors and Sheaths, facilitate placement of the Sling and are not implanted.

The ArcTO Sling assembly is identical to the predicate, ArcTV Sling assembly and includes one knitted polypropylene mesh with an integrated bioresorbable Suture, two removable plastic insertion Sheaths, and two Sling Connectors. The Suture is an integral feature of the Mesh. The integrated Suture helps to minimize deformation of the mesh during sling insertion and placement and allows for adjustment of the Sling after removal of the Sheaths. The two plastic Sheaths cover and facilitate placement of the Sling. The Mesh and the bioresorbable Suture are permanently implanted.

7.8 INTENDED USE

Implantable Sling intended to treat female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

7.9 INDICATIONS FOR USE

The polypropylene sling is indicated to be placed mid-urethra for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).

7.10 PERFORMANCE DATA

The ArcTO Transobturator Sling System has been tested to meet the device's intended use and to ensure conformance to the product specifications.

The ArcTO meets all its physical and performance specifications including:

- Dimensional
- Needle Functional Testing
- *Sling Functional Testing
- *Fatigue
- *Tensile
- Packaging Testing

- Usability Testing
- Distribution Testing
- *Biocompatibility

* No testing was repeated for this submission since the Sling implant assembly is identical to the predicate, ArcTV.

7.11 DEVICE COMPARISON

The ArcTO Transobturator Sling System consists of the following:

- 1 ArcTO Sling with bio-resorbable Suture and plastic sheath
- 2 ArcTO Handle and Needle Delivery Assemblies

The ArcTO Transobturator Sling is identical to the predicate sling, ArcTV. The delivery of the sling is the outside-in transobturator approach for the subject device (ArcTO) versus transvaginal for the predicate device (ArcTV); therefore, the shape of the needle has changed to facilitate an outside-in transobturator delivery. The mid-urethral placement of the sling is the same for both. The different Needle designs specific patient considerations and physician surgical preferences.

The following table compares the subject device, ArcTO to the predicate device, ArcTV and the reference device, Monarc.

Table 7-1: Comparison of Device Characteristics to Marketed Predicate Device

Device Characteristics	Subject Device ArcTO Transobturator Sling System	Predicate Device ArcTV Transvaginal Sling System (K183134)	Reference Device Monarc Sling System (K131229)
Intended Use	**Same as predicate** Implantable Sling intended to treat female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).	Implantable Sling intended to treat female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).	Implantable Sling intended to treat female stress urinary incontinence resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).
Indication for Use	**Same as predicate** The polypropylene sling is indicated to be placed mid-urethra for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).	The polypropylene sling is indicated to be placed mid-urethra for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).	Intended for the placement of pubourethral sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency.

Device Characteristics	Subject Device ArcTO Transobturator Sling System	Predicate Device ArcTV Transvaginal Sling System (K183134)	Reference Device Monarc Sling System (K131229)
Regulation Number and Product Code	**Same as predicate**	878.3300 OTN	878.3300 OTN
Regulatory Classification Name	**Same as predicate**	Surgical mesh	Surgical mesh
Device Configuration	**Same as predicate**	Single use, sterile device	Single use, sterile device
Entry Method	**Same as technological reference**	Transvaginal Retropubic	Outside-in Transobturator
Delivery System	**Same as technological reference**	Handle with detachable curved Needle	Helical needle with attached handle
Sling	**Same as predicate**	Sheathed polypropylene mesh with adjustment bioresorbable suture	Sheathed polypropylene mesh with adjustment bioresorbable suture
Sterilization	**Same as predicate**	EO, SAL 10^{-6}, single use	EO, SAL 10^{-6}, single use
Biocompatibility	**Same as predicate**	Meets ISO 10993-1:2009, Biological evaluation of medical devices requirements	Meets ISO 10993-1:2009, Biological evaluation of medical devices requirements
Packaging	**Same as predicate** Molded tray shape is changed	Molded tray with Tyvek lid and separate pouch for Sling	Molded tray with Tyvek lid and separate pouch for Sling

7.12 SUBSTANTIAL EQUIVALENCE

The ArcTO Transobturator Sling System covered by this submission is substantially equivalent to the predicate ArcTV Transvaginal Sling System device (K183134). The minor difference in the shape and size of the needle to optimize the ArcTO's outside-in transobturator needle passage and technique do not raise new safety and efficacy as the shape, size and stiffness of the needle is the same as the technological reference.

7.13 CONCLUSION

Since the implantable sling assembly system is identical to the predicate, ArcTV, and the intended use is the same, the ArcTO is substantially equivalent to its predicate. The minor difference in the shape and size of the needle does not raise any new questions of safety or efficacy.