February 7, 2019

UroCure LLC
% Ming-Cheng Chew
Regulatory Consultant
Libra Medical, Inc.
8401 73rd Ave No., Suite 63
Brooklyn Park, MN 55428

Re: K183134
Trade/Device Name: ArcTV Transvaginal Sling System
Regulation Number: 21 CFR 878.3300
Regulation Name: Surgical Mesh
Regulatory Class: Class II
Product Code: OTN
Dated: January 9, 2019
Received: January 11, 2019

Dear Ming-Cheng Chew:

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/CombinationProducts/GuidanceRegulatoryInformation/ucm597488.htm); 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 http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/) and CDRH Learn (http://www.fda.gov/Training/CDRHLearn). 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 (http://www.fda.gov/DICE) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Glenn B. Bell -S

for
Benjamin R. Fisher, Ph.D.
Director
Division of Reproductive, Gastro-Renal,
and Urological Devices
Office of Device Evaluation
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K183134

Device Name
ArcTV Transvaginal Sling System

Indications for Use *(Describe)*

The ArcTV Transvaginal Sling System is a retropubic sling indicated for a transvaginal (TV) placement of a mid-urethral sling for the treatment of adult 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.

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1 510(K) SUMMARY

1.1 ADMINISTRATIVE INFORMATION

Date of Summary Preparation: 1/9/2018

1.2 CONTACT INFORMATION

Primary Submission Contact
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1.3 DEVICE INFORMATION

Trade Name	ArcTV Transvaginal Sling System
Common Name	Urinary sling
Classification Name	Surgical Mesh
Classification Regulation	878.3300
Class	II
Panel	Gastroenterology/Urology
Product Code	OTN
Product Code Name	Mesh, Surgical, Synthetic, Urogynecologic, For Stress Urinary Incontinence, Retropubic Or Transobturator

1.4 510(K) TYPE AND REASON FOR SUBMISSION

This 510(k) is a traditional 510(k) and is submitted to obtain marketing clearance for a new device – the ArcTV Transvaginal Sling System.

1.5 PREDICATE DEVICE

RetroArc Repubic Sling System (K132655)

1.6 DEVICE DESCRIPTION

The ArcTV Transvaginal Sling System is a sterile, single-use system, consisting of a Handle, two delivery Needles and a Sling assembly. The tip portion of each delivery Needle is configured to allow for passage through tissue. The opposite end of the Needle is configured to connect with

the Handle. The Handle is detachable and is used to direct both delivery Needles through tissue. The Sling assembly includes one piece of loosely knitted polymeric 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 Suture and Mesh allow for adjustment of the Sling after initial placement in the patient without the use of additional tools. The two plastic Sheaths facilitate the placement of the Sling.

The Sling Connectors, Sheaths, Needles, and Handle are used to facilitate placement of the Sling assembly, and are not implanted. The Mesh and the bioresorbable Suture are permanently implanted.

1.7 INDICATIONS FOR USE

The ArcTV Transvaginal Sling System is a retropubic Sling indicated for a transvaginal (TV) placement of a mid-urethral Sling for the treatment of adult female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD)

1.8 PERFORMANCE DATA

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

The ArcTV meets all its physical and performance specifications including:

- Dimensional
- Fatigue
- Tensile
- Packaging Testing
- Usability Testing
- Distribution Testing

In addition, the ArcTV was tested for biocompatibility per ISO 10993-1:2009 for external communicating device with tissue for limited duration contact with (<24 hours) for the Needle and Handle, and for permanent implant in tissue (>30 days) for the Mesh and Suture.

1.9 SUBSTANTIAL EQUIVALENCE

Device Characteristics	ArcTV Transvaginal Sling System	AMS RetroArc Retropubic Sling System (K132655)
Intended Use	The ArcTV Transvaginal Sling System is intended to treat female stress urinary incontinence.	Same

Device Characteristics	ArcTV Transvaginal Sling System	AMS RetroArc Retropubic Sling System (K132655)
Indication for Use	The ArcTV Transvaginal Sling System is a retropubic Sling indicated for a transvaginal (TV) placement of a mid-urethral Sling for the treatment of adult female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD)	The RetroArc Retropubic Sling System is intended for the placement of a suburethral Sling for the treatment of female stress urinary incontinence (SUI) resulting from urethral hypermobility and/or intrinsic sphincter deficiency (ISD).
Entry Method	Transvaginal Retropubic	Same
Delivery System	Handle with detachable curved Needle	Same
Sling	Sheathed polypropylene mesh with adjustment bioresorbable suture	Same
Sterilization	EO, SAL 10^{-6}, single-use	Same
Packaging	Molded tray with Tyvek lid and separate pouch for Sling	Same

1.10 CONCLUSION

Based on the test data and the same intended use, the ArcTV is substantially equivalent to its predicate. The minor differences do not raise any new questions of safety or efficacy.