June 23, 2023

On-X Life Technologies, Inc.
John Ely
Executive Vice President
1300 East anderson Lane
Building B
Austin, Texas 78752

Re: K141060
Trade/Device Name: Chord-X Pre-measured Loops For Mitral Chordal Replacement
Regulation Number: 21 CFR 878.3470
Regulation Name: Intracardiac patch or pledget made of polypropylene, polyethylene terephthalate, or polytetrafluoroethylene
Regulatory Class: Class II
Product Code: PAW

Dear John Ely:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated June 6, 2014. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under 21 CFR 878.3470.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Jaime Raben, OHT2: Office of Cardiovascular Devices, (301)796-1137, jaime.raben@fda.hhs.gov.

Sincerely,

Jaime Raben -S

Jaime Raben
Assistant Director
DHT2B: Division of Circulatory Support,
Structural and Vascular Devices
OHT2: Office of Cardiovascular Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

June 6, 2014

On-X Life Technologies, Inc.
John Ely
Executive Vice President
1300 East Anderson Lane
Building B
Austin, Texas 78752

Re: K141060
Trade/Device Name: Chord-x pre-measured loops for mitral chordal replacement
Regulation Number: 21 CFR 878.5035
Regulation Name: Non-Absorbable Expanded Polytetrafluoroethylene Surgical Suture
Regulatory Class: Class II
Product Code: PAW
Dated: May 6, 2014
Received: May 7, 2014

Dear Mr. Ely,

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 yours,

for Bram D. Zuckerman, M.D.
Director
Division of Cardiovascular Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number: K141060

Device Name: Chord-X Pre-Measured Loops for Mitral Chordal Replacement

Indications for use:

Chord-X Pre-Measured Loops for Mitral Chordal Replacement are indicated for the repair or replacement of chordae tendinae.

Prescription Use _____YES_____ AND/OR Over-the-counter Use _____

Concurrence of CDRH, Office of Device Evaluation (ODE)

JUN 0 6 2014

510(k) Summary (K141060) **Date: June 4, 2014**

Company Name, Address and Contacts

On-X Life Technologies, Inc.
1300 East Anderson Lane, Bldg B
Austin, TX 78752
Telephone: 512-339-8000 X226
Contact Person: John Ely

Establishment Registration Number: 1649833

Device Information

Proprietary Name: Chord-X Pre-Measured Loops for Mitral Chordal Replacement
Common Name: ePTFE suture
Classification Name: Non-absorbable expanded polytetrafluoroethylene surgical suture
Review Panel: Cardiovascular
Classification: 21CFR878.5035
Product code: PAW
Class: II
Substantial Equivalence:
Chord-X ePTFE Suture - KI21173 - On-X Life Technologies, Inc.
Tetraflouroethylene (TFE) Polymer Pledget - K953289 - Davis and Geck - Now Covidien

Device Description

The device is a non-absorbable monofilament ePTFE suture using 4 Chord-X ePTFE sutures in a looped configuration provided in the following sizes and meeting the USP standards:

	2-0 Suture			
	22mm Taper Point Needle		**18mm Taper Point Needle**	
Loop Length	3/8 Circle	1/2 Circle	3/8 Circle	1/2 Circle
Adjustable	CXL-20-2238-0	CXL-20-2212-0	CXL-20-1838-0	CXL-20-1812-0
12mm	CXL-20-2238-12	CXL-20-2212-12	CXL-20-1838-12	CXL-20-1812-12
16mm	CXL-20-2238-16	CXL-20-2212-16	CXL-20-1838-16	CXL-20-1812-16
20mm	CXL-20-2238-20	CXL-20-2212-20	CXL-20-1838-20	CXL-20-1812-20
24mm	CXL-20-2238-24	CXL-20-2212-24	CXL-20-1838-24	CXL-20-1812-24

	3-0 Suture			
	22mm Taper Point Needle		18mm Taper Point Needle	
Loop Length	3/8 Circle	1/2 Circle	3/8 Circle	1/2 Circle
Adjustable	CXL-30-2238-0	CXL-30-2212-0	CXL-30-1838-0	CXL-30-1812-0
12mm	CXL-30-2238-12	CXL-30-2212-12	CXL-30-1838-12	CXL-30-1812-12
16mm	CXL-30-2238-16	CXL-30-2212-16	CXL-30-1838-16	CXL-30-1812-16
20mm	CXL-30-2238-20	CXL-30-2212-20	CXL-30-1838-20	CXL-30-1812-20
24mm	CXL-30-2238-24	CXL-30-2212-24	CXL-30-1838-24	CXL-30-1812-24

All configurations are supplied with two (2) 0.118 X 0.276 X 0.059 inches (3 X 7 X 1.5 mm) pledgets. All suture strands used in the construction of the prosthesis are 32 inches in length.

The loops are made simply as a convenience for the surgeon who currently must tie these at the operating table as described in the medical literature (Gillinov AM, Banbury MK. Pre-Measured Artificial Chordae for Mitral Valve Repair. *Ann Thorae Surg* 2007;84:2127-2129.) It eliminates a step in the operation. They are provided as sterile, single use products and contain no dyes or additives.

Intended Use

Chord-X Pre-Measured Loops for Mitral Chordal Replacement are indicated to be used in repair or replacement of chordae tendinae.

Summary of Technological Characteristics

Characteristic	Chord-X Loops	Chord-X ePTFE Suture	Covidien Pledget
Material(s)	ePTFE monofilament	ePTFE monofilament	PTFE felt
Intended Use	Chordal repair	Chordal repair	Cardiovascular suture buttress
Meets USP	Yes	Yes	NA
Configuration	USP 2-0 and 3-0 with pledgets	USP 2-0 and 3-0	3 X 7 X 1.5 mm with 2 holes
Needle Choices	3/8 and ½ circular taper point	3/8 and ½ circular taper point	NA
Packaging	Case within a peel-pouch	Double peel-pouch type	--
Knot Pull Tensile Strength (2-0)	4.85 lbf	4.85 lbf	--
Stiffness	62779 kgf	62779 kgf	--
% Elongation	2.23%	2.23%	--

Usage	Single use	Single use	Single use
Sterilized	EtO	EtO	--
Shelf Life	3-year	3-year	--

Biological Test Data of Chord-X Pre-Measured Loops

Biological Endpoint		**Results**
Cytotoxicity		Grade 0, Non-Cytotoxic
Sensitization		Non-Sensitizer
		Non-Sensitizer
Intracutaneous Irritation		Nonirritant
		Nonirritant
Acute Systemic Toxicity		No signs of acute, systemic toxicity
		No signs of acute, systemic toxicity
Material Mediated Pyrogenicity		Nonpyrogenic
Hemocompatibility	ASTM Hemolysis – Direct Contact	Nonhemolytic
	ASTM Hemolysis - Extraction	Nonhemolytic
	C3a Complement Activation	Not an activator
	SC5b-9 Complement Activation	Not an activator

Physicochemical Results following Exhaustive Extraction of the Chord-X Loops

Extraction Vehicle	**Sample Amount**	**Number of Extractions**	**Residue Mass**	**Residue Mass/cm Length**
PW	123.7 cm^2 89.5 cm length	2	0.2 mg	0.002 mg
Ethanol	127.2 cm^2 90.0 cm length	2	0.4 mg	0.004 mg
Hexane	127.2 cm^2 89.5 cm length	2	0.5 mg	0.006 mg

Infrared Scans of the Residues Obtained from the Chord-X Loops

Extraction Vehicle	IR Match	NAMSA Lab Number
PW	No major bands detected	12T_20903_15
Ethanol	No major bands detected	12T_20903_16
Hexane	No major bands detected	12T_20903_17

Shelf Life

Testing to validate shelf life for Chord-X Pre-Measured Loops final packaging was conducted as per the requirements listed in ISO 11607-1. An accelerated aging method per the appropriate reference standard has been employed to simulate actual shelf life duration to 3-years. Sterile barrier and product integrity tests confirm that the package is robust enough to withstand shipping and storage for at least 3-years.

Sterilization

Ethylene oxide (EO) is used to sterilize the Chord-X Pre-Measured Loops and the process is validated to ISO 11135-1. The sterilization validation established that the process and product meet the requirements of the standard.