July 6, 2023

Cynosure, LLC
Cynthia Aguirre
Regulatory Affairs Specialist II
5 Carlisle Road
Westford, Massachusetts 01886

Re: K230510
Trade/Device Name: MyEllevate
Regulation Number: 21 CFR 878.5000
Regulation Name: Nonabsorbable Poly(Ethylene Terephthalate) Surgical Suture
Regulatory Class: Class II
Product Code: GAT
Dated: April 14, 2023
Received: April 17, 2023

Dear Cynthia Aguirre:

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,

Alexander Nguyen -S

Digitally signed by Alexander Nguyen -S
Date: 2023.07.06 16:23:26 -04'00'

for Cynthia J. Chang, Ph.D.
Director
DHT4B: Division of Infection Control
and Plastic 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)*
K230510

Device Name
MyEllevate

Indications for Use *(Describe)*
MyEllevate is indicated for use in soft tissue approximation and elevation of sub dermis and underlying muscle

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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Section 5- 510(K) Summary

510(k) Summary for Cynosure MyEllevate

A summary of 510(k) safety and effectiveness information in accordance with the requirements of 21 CFR 807.92.

807.92(a)(1) Submitter Information	
Applicant	Cynosure, LLC
Address	5 Carlisle Road, Westford MA, 01886
Phone Number	480-401-9884
Fax Number	N/A
Establishment Registration Number	1222993
Contact Person	Cynthia Aguirre
Preparation Date	July 6, 2023
807.92(a)(2) Name of Device	
Trade or Proprietary Name	MyEllevate
Common or Usual Name	Nonabsorbable Polyester Suture
Classification Name	Nonabsorbable poly(ethylene terephthalate) surgical suture
Classification Panel	General & Plastic Surgery
Regulation	21 CFR, §878.5000
Regulatory Class	II
Product Code(s)	GAT
807.92 (a)(3) Legally marketed device(s) to which equivalence is claimed	
Predicate Devices	Implicitguide™ Surgical Suture System (K091061) TEVDEK ® Polyester Suture (K1001434, K021019)
807.92(a)(4) Device Description	
	The MyEllevate device consists of a Surgical Suture System consisting of synthetic non-absorbable, braided, polyester surgical suture, and a set of instruments designed to efficiently and accurately place the suture for the purpose of performing soft tissue approximation. MyEllevate contains a Skin Marking Tape, a Lancet, a Tunneling Rod, two stainless steel Suturods, and a Light Handle which contains an LED light source. Each Suturod™ has an internal fiber optic “light pipe” which, when connected to the Ligh Handle, illuminates the distal tip of the Suturod™ and permits visual verification of the location and depth of the Suturod™ as it is passed through the subcutaneous space. All components of MyEllevate are provided sterile and are intended for single use only. While the nonabsorbable suture is a Class II device as describes by 21CFR, §878.5000, the

	remaining instruments are Class I devices exempt from 510(k) requirements. The Lancet, Clearing Device, and Tunneling Rod are manual surgical devices described by 21 CFR §878.4800. The Skin Marking Pen is described in 21 CFR §878.4660, and the fiber optic "light pipe" and Light Handle to illuminate surgical sites, is described in 21 CFR, §876.4530.
807.92(a)(5) Intended Use of the Device	
	The MyEllevate device is indicated for soft tissue approximation and elevation of sub dermis and underlying muscle.
807.92(b)(1) Non-clinical tests submitted	
The following non- clinical tests have been included in this 510(k) submission in determination of substantial equivalence between the test device and the referenced predicates. **Electromagnetic Compatibility and Electrical Safety** Performance testing was conducted for MyEllevate to demonstrate that the device satisfies electrical safety requirements of the following standards: • IEC 60601-1:2005/AMD1L2012 & AMD2:2020 Medical Electrical Equipment Part 1: General requirements for basic safety and essential performance • IEC 60601 60601-1-2: Ed 4.1 Medical Electrical Equipment Part 1-2: General requirements for basic safety and essential performance – Collateral standard: Electromagnetic Compatibility – Requirements and Tests • IEC 60601-1-6:2005/AMD1:2012 & AMD2:2020Medical Electrical Equipment Part 1-6: General requirements for basic safety and essential performance – Collateral standard: Usability IEC 62471: 2008 Photobiological safety of lamps and lamp system	
807.92(b)(2) Clinical tests submitted – N/A – No clinical tests submitted	
807.92(b)(3) Conclusions drawn from clinical and non-clinical tests submitted	
The results of our comparisons demonstrated the substantial equivalence of the subject device to the identified predicate devices.	

Device	**MyEllevate** (K230510)	**Implicitguide™ Surgical Suture System** (K091061)	**TEVDEK ® II Suture** (K001434, K021019)
Indication for Use	The MyEllevate device is indicated for soft tissue approximation and elevation of sub dermis and underlying muscle.	The Implicitguide™ Surgical Suture System is indicated for use in soft tissue approximation and elevation of sub dermis and underlying muscle	Soft tissue approximation
Suture Composition	Poly (Ethylene terephthalate)	Poly (Ethylene terephthalate)	Poly (Ethylene terephthalate)
Suture Construction	Braided	Braided	Braided
Suture Color	Undyed (Natural) Dyed (green)	Undyed (Natural) Dyed (green)	Undyed (Natural) Dyed (green)
Suture Size	USP 4-0	USP 4-0	USP 4-0
USP Official Monograph	Conforms	Conforms	Conforms
<861> *Suture Diameter*	Conforms	Conforms	Conforms
<881> *Tensile Strength*	Conforms	Conforms	Conforms
Attached Needles	Yes	Yes	Yes
Needle Composition	Stainless Steel	Stainless Steel	Stainless Steel
<871> *Needle attachment- Sutures*	Conforms	Conforms	Conforms

Manufacture	Cynosure, LLC.	ImplicitCare, LLC.	Teleflex
How Supplied	Sterile; single- use	Sterile; single- use	Sterile; single- use
Sterilization Method	Ethylene oxide	Ethylene oxide	Ethylene oxide
Biocompatibility	Meets ISO 10993-1	Meets ISO 10993-1	Meets ISO 10993-1
Additional instruments	Manual surgical instruments per §878.4800 supplied	Manual surgical instruments per §878.4800 supplied	Manual surgical instruments per §878.4800 supplied