May 10, 2023

Sientra, Inc.
Denise Dajles
SVP R&D, Regulatory and Quality
420 South Fairview Avenue
Suite 200
Santa Barbara, California 93117

Re: K221127
Trade/Device Name: Sientra, inc. Portfinder
Regulatory Class: Unclassified
Product Code: LCJ
Dated: April 17, 2023
Received: April 20, 2023

Dear Denise Dajles:

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,

Deborah A. Fellhauer -S

Deborah Fellhauer RN, BSN
Assistant 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)*
K221127

Device Name
Portfinder

Indications for Use *(Describe)*
The Sientra Portfinder is a battery-operated standalone port detection device that is intended for use with the Sientra AlloX2 Pro and Dermaspan Tissue Expanders.
The Portfinder is an electronic handheld injection port detector device that externally locates subcutaneous ports of an implanted tissue expander, enabling fill of the tissue expander or use of the drain system.
The enclosed device is nonsterile and for postoperative use only.

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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510(k) Summary

Date Prepared: May 10, 2023

Submitter:
Sientra, Inc.
3333 Michelson Dr. Suite 650
Irvine, California 92612

Contact:
Denise Dajles
SVP R&D, Regulatory and Quality
Sientra, Inc.
949-739-9255
denise.dajles@sientra.com

Proprietary Name: Portfinder

Common Name: Injection Port Detector

Classifications:
Unclassified (pre-amendment)
Product Code: LCJ

Classification Panel: General & Plastic Surgery

Substantially Equivalent Device: Mentor Corp. Mentor injection Port Detector (K963066)

Intended Use / Indications:

The Sientra Portfinder is a battery-operated standalone port detection device that is intended for use with the Sientra AlloX2 Pro and Dermaspan Tissue Expanders.

The Portfinder is an electronic handheld injection port detector device that externally locates subcutaneous ports of an implanted tissue expander, enabling fill of the tissue expander or use of the drain system.

The enclosed device is nonsterile and for postoperative use only.

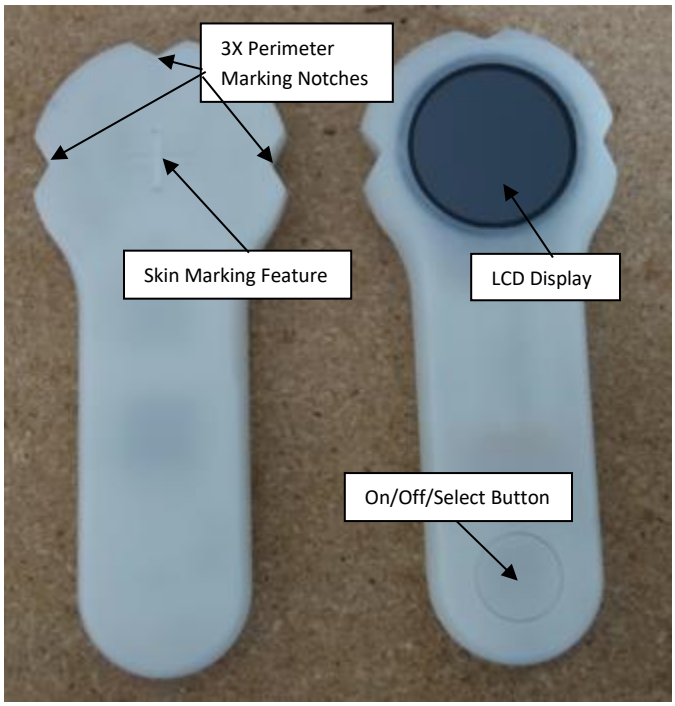
Device Description:

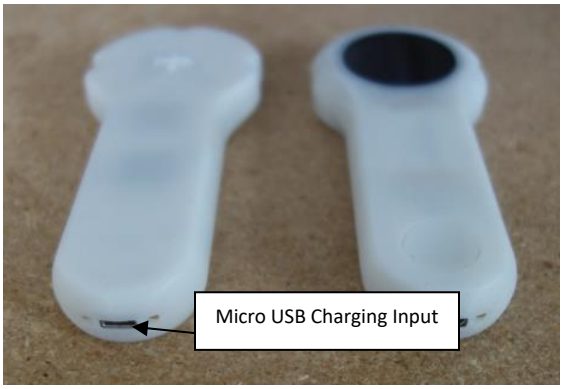
The Portfinder is an electronic handheld injection port detector device that externally locates subcutaneous ports of an implanted tissue expander. The Portfinder is intended to locate the fill and drain ports of the Sientra AlloX2 Pro Breast Tissue Expanders (AlloX2 Pro) and fill port of the Sientra OPUS Dermaspan Breast Tissue Expanders (Dermaspan); enabling the user to mark the location of the ports for subsequent fill and drain of the respective tissue expander.

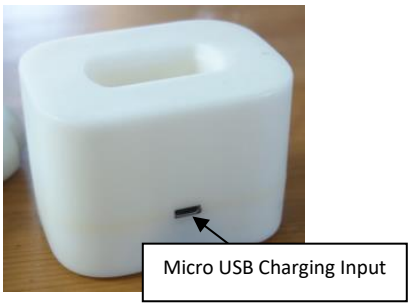
The Portfinder contains an LCD screen that displays the location of the intended port (drain or fill port). A single button of the Portfinder is used to power on/off and change modes.

The Portfinder housing has features to temporarily indent the port location on the surface of the skin or use a skin marker to mark the port location.

The Portfinder is intended to be used by clinicians in medical settings such as hospitals and medical clinics. It can be disinfected between uses for multi-patient reuse.







Substantial Equivalence Discussion:

The proposed Portfinder and its predicate device, Mentor Corp. Mentor Injection Port Detector (K963066), are similar in regards to their intended use, clinical indications, principle of operation and fundamental technology. Sientra concludes that the

Portfinder does not introduce any new potential safety and/or effectiveness issues and is substantially equivalent to the identified predicate device, Mentor Injection Port Detector (K963066).

Characteristic	**Proposed** **Sientra, Inc.** **Portfinder** **(K221127)**	**Predicate** **Mentor Corp.** **Injection Port Detector** **(K963066)**
Regulatory		
Regulation Number	N/A	N/A
Regulation Name	N/A	N/A
Regulatory Class	Unclassified (pre-amendment)	Unclassified (pre-amendment)
Product Code	LCJ	LCJ
Common Name	Expander, Skin, Inflatable	Expander, Skin, Inflatable
Indications for Use	The Sientra Portfinder is a battery-operated standalone port detection device that is intended for use with the Sientra AlloX2 Pro and Dermaspan Tissue Expanders. The Portfinder will locate the port(s) subcutaneously, enabling fill of the tissue expander or use of the drain system. The enclosed device is nonsterile and for postoperative use only.	The Mentor H/S Injection Port detector is used to detect Mentor Tissue Expander remote and integral injection ports. The device is nonsterile and for postoperative use only.
Intended Use	The Portfinder can be used to detect and locate Sientra AlloX2 Pro and Dermaspan Tissue Expander subcutaneous fill and drain ports.	The detector can be used to detect Mentor tissue expander standard remote and integral injection ports.
Sterility	Supplied nonsterile / not sterilizable	Supplied nonsterile / not sterilizable
Reuse	Multi-patient use, cleaned and disinfection prior to use using a 70% IPA wipe.	Multi-patient use, cleaned and disinfection prior to use with IPA swab or antibacterial soap and water. The device cannot be immersed in liquid or allow liquid to enter the device.
Contraindications	Dermaspan or AlloX2 Pro subcutaneous ports implanted	Mentor integral injection ports implanted more than 2” and

Characteristic	Proposed Sientra, Inc. Portfinder (K221127)	Predicate Mentor Corp. Injection Port Detector (K963066)
	more than 40mm or less than 5mm below the surface of the skin cannot be located accurately with this device. The use of the Portfinder in these situations is contraindicated. The use of the Portfinder near a magnetic field may interfere with the device. It may be necessary to move the interfering equipment farther away or move the patient to another room in order to properly use the device. The use of the Portfinder is not recommended in patients with metallic or magnetic devices located internally or externally near the subcutaneous port.	standard remote injection ports implanted more than 1.4” below the surface of the skin cannot be located accurately with this device. The use of the detector in these situations is contraindicated. The use of the detector near an electromagnetic field may interfere with device tuning. It may be necessary to move the interfering equipment farther away or move the patient to another room in order to properly use the device. The use of the detector is not recommended in patients with metallic or magnetic devices located internally or externally near the injection port.
Configuration and Accessories		
Accessory to tissue expander	Portfinder is an accessory to Sientra AlloX2 Pro and Dermaspan Tissue Expanders	The detector is an accessory to Mentor tissue expanders
Included components to detector	Charging base and cord is included	No accessories included
Technological Characteristics		
Hand-held	Yes	Yes
Battery Powered	Yes	Yes
Rechargeable	Yes – charging base or via charging port on handheld device	No – replaceable 9V battery
Software Controlled	Yes	Yes
Operating Principle	Array of magnetometers used as hall effect sensors to	Electromechanical coils detect changes in magnetic field. Magnetic field changes near

Characteristic	Proposed Sientra, Inc. Portfinder (K221127)	Predicate Mentor Corp. Injection Port Detector (K963066)
	detect the center of the magnetic field. The sensors operate as analog transducers, directly returning a voltage. Using groups of sensors, the relative position of the magnet is displayed on the screen and the screen displays when the center of the port has been located.	the injection port, inducing a current in the coils. LED display indicated when center of port has been located.
Self-calibrating	Yes – when powered on, mode screen will appear	Yes – when powered on, indicator turns green
Compatible Ports	Portfinder will locate Sientra AlloX2 Pro and Dermaspan Tissue Expander integral injection ports	Detector locates Mentor tissue expander integral injection ports and standard remote injection ports
Location Modes	Fill Drain (AlloX2 Pro only)	Fill
User Interface	Display screen on handheld device 	Directional arrows that illuminate 
Detection Indicator	Position cursor (indicator) will be concentric with the target at the screen center. The position cursor and center target will turn green to indicate successful alignment with the desired tissue expander port.	Directional arrows rotating when detection in progress. When complete, all direction arrows stop and turn green.
Marking of Port Location	Portfinder features two methods for marking the port location. <u>Option 1: Skin Marking Feature</u>	Detector features a Skin Marking Plunger for marking the port location. Using the button on the top of the device, the plunger is

Characteristic	Proposed Sientra, Inc. Portfinder (K221127)	Predicate Mentor Corp. Injection Port Detector (K963066)
	The feature is depressed into the tissue and removed; the center of the cross is then marked with a skin marking pen. <u>Option 2: Perimeter Marking Notches</u> The skin is marked at the apex of each of the three perimeter notches on the Portfinder. Perpendicular lines are drawn with a skin marker to mark the port center location. 	depressed into the skin and leaves a circular mark which can be marked with skin marker or immediately injected through.
Patient Contacting Materials	Device outer case, button and charging base case injection molded from Avient Mevopur-White NC0M820283 (Avient blend of Makrolon 2458 and Eggshell colorant)	Unknown plastic

Bench Testing:

Design verification tests were performed on the Portfinder as a result of the risk analysis and product requirements. Sientra has determined that the modifications have no impact on the safety and effectiveness of the device.

Software Verification and Validation testing was performed on Portfinder, and documentation is provided as recommended by FDA's Guidance for Industry and FDA Staff, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". The software is considered as a "moderate level of concern" since a

failure or latent design flaw could lead to an erroneous diagnosis or a delay in delivery of appropriate medical care that would likely lead to Minor Injury. The Verification and Validation testing was performed in accordance with IEC 62304:2006/A1:2016 to assess the safety and effectiveness of the device, via system level testing.

Clinical Testing:

Clinical testing was not necessary to demonstrate substantial equivalence of Portfinder to the predicate device.

Overall Conclusion:

Based on the information presented in this submission, Sientra concludes that Portfinder is substantially equivalent to the predicate devices in regard to indications, principles of operation, and technological characteristics. Additionally, verification and validation tests demonstrate the safety and efficacy of the device to meet its intended use and specifications. Sientra believes that the proposed device, Portfinder, is substantially equivalent to the identified predicate device and is as safe and effective as its predicate device without raising any new safety and/or effectiveness concerns.