June 8, 2023

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

Re: K214124
Trade/Device Name: AlloX2 Pro Tissue Expanders
Regulatory Class: Unclassified
Product Code: LCJ
Dated: January 12, 2023
Received: January 17, 2023

Dear Denise Daljes:

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,

David Krause -S

David Krause, Ph.D.
Deputy Director
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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*

K214124

Device Name
Sientra AlloX2 Pro Tissue Expanders

Indications for Use *(Describe)*

The Sientra AlloX2 Pro Tissue Expanders are intended for temporary (less than six months) subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in reconstructions following mastectomy, to aid in the treatment of underdeveloped breasts and to aid in treatment of soft tissue deformities.
Additionally, the Sientra AlloX2 Pro Tissue Expanders contain a silicone drain component which allows access to and drainage of latent fluids from the periprosthetic space. This drain component does not replace short-term, immediate, intraoperatively placed drains.

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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6.0 510(k) Summary [807.92(a)(1)]

Sponsor: Sientra, Inc.
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Date Prepared: May 31, 2023

Device Information [807.92(a)(2)]

Regulatory Classification:	Unclassified (pre-amendment)
Product Code:	LCJ
Proprietary Name:	Sientra AlloX2 Pro™ Tissue Expander
Device Classification Name:	Expander, Skin, Inflatable
Review Panel:	General and Plastic Surgery Devices Panel
Predicate Device:	Sientra AlloX2 Tissue Expander (K140383)

Indications for Use [807.92(a)(5)]

The Sientra AlloX2 Pro Tissue Expanders are intended for temporary (less than six months) subcutaneous or submuscular implantation to develop surgical flaps and additional tissue coverage required in a wide variety of applications, particularly to aid in reconstructions following mastectomy, to aid in the treatment of underdeveloped breasts and to aid in treatment of soft tissue deformities.

Additionally, the Sientra AlloX2 Pro Tissue Expanders contain a silicone drain component which allows access to and drainage of latent fluids from the periprosthetic space. This drain component does not replace short-term, immediate, intraoperatively placed drains.

Predicate Device [807.92(a)(3)]

The Sientra AlloX2 Pro Tissue Expander is substantially equivalent in respect to intended use, indications for use, device materials, performance, sterilization, and biocompatibility to the predicate device the Sientra AlloX2 Tissue Expander, cleared under K140383.

Device Description [807.92(a)(4)]

The Sientra AlloX2 Pro Tissue Expanders are constructed from silicone elastomer and consist of an expansion envelope with a smooth surface and an integrated magnetically locatable port system for incremental expander filling. The Sientra AlloX2 Pro Tissue Expanders have an incorporated drainage system accessed by a drain port. The incorporated drain system allows for aspiration of fluids from the periprosthetic space that may present during the expansion process. Both the integrated fill and drain ports can be accessed with an 18- gauge needle or smaller. The AlloX2 Pro Tissue Expanders have suture tabs providing an option for surgeons to suture the expander within the breast pocket. The AlloX2 Pro Tissue Expanders are labeled Magnetic Resonance (MR) Conditional. Patients implanted with the AlloX2 Pro Tissue Expanders may undergo Magnetic Resonance Imaging under specific MR conditions. The potential resulting risks associated with using the device in the MRI environment include the inability to fill the device, loss of port location functionality and potential reoperation should the patient require continued function of the tissue expander device after MRI exposure.

The Sientra AlloX2 Pro Tissue Expanders are manufactured in both mid-height and full-height base options from 11 cm to 16 cm to meet diverse patient needs and to achieve individualized aesthetic results. The Sientra AlloX2 Pro Tissue Expanders are supplied sterile. The Sientra AlloX2 Pro Tissue Expander accessories include a magnetic port locating device (PRO Locator) that allows for simultaneous identification of the fill and drain ports for ease of identification, and a 21-gauge winged needle infusion set. Both are supplied sterile and individually packaged inside the product box.

Comparison of Technological Characteristics with the Predicate Device [807.92(a)(6)]

The proposed device, the Sientra AlloX2 Pro Tissue Expanders are substantially equivalent to the predicate device, as they share the same function, intended use and indications for use. Any difference in technological characteristics do not raise any new issues of safety or efficacy.

The Sientra AlloX2 Pro Tissue Expander shell is constructed of the same materials of construction, the proposed Sientra AlloX2 Pro Tissue has a smooth surface only. Both the proposed and predicate devices include an expansion envelope with an integrated magnetically locatable port system for incremental expander filling in order to develop a surgical flap and an incorporated drainage system accessed by a drain port providing access to the periprosthetic space. While both devices have integral fill and drain ports and both use magnets for port location, the proposed device fill and drain ports are made of an implant grade polymer instead of titanium. The proposed device design allows for the use of an 18-gauge needle or smaller with the fill and drain ports as compared to the predicate device which is labeled for use with a 21-gauge needle or smaller. The proposed device includes suture tabs providing an option for surgeons to suture the expander within the breast pocket.

Both the predicate device and proposed device utilize a magnetically accessible port system and use a port location accessory (provided with the product) to enable identification of the integrated fill and drain ports. The predicate product magnetic port location accessory identifies the device ports individually, while the subject device PRO Locator, simultaneously identifies both the fill and drain ports which are clearly marked, “fill” and “drain”. As with the predicate, the proposed device is packaged with a sterile 21-gauge winged needle infusion set that is individually packaged and may be used for injection into or aspiration from the respective fill and drain ports. There have been no changes to the winged needle since the predicate clearance (K140383).

Both accessory products, including the PRO Locator and 21-gauge needle winged needle set are provided sterile and are packaged in a sterile barrier packaging.

The proposed AlloX2 Pro Tissue Expanders have Magnetic Resonance (MR) Conditional labeling and patients implanted with the AlloX2 Pro Tissue Expanders may undergo Magnetic Resonance Imaging under specific MR conditions, as indicated in the labeling.

Traditional 510(k) Premarket Notification

Performance Data [807.92(b)]

All necessary performance testing was conducted to support a determination of substantial equivalence of the Sientra AlloX2 Pro Tissue Expanders to the predicate device.

Non-clinical Testing Summary [807.92(b)(1)]

Sterilization and Shelf Life

The Sientra AlloX2 Pro Tissue Expander is provided sterile with a Sterility Assurance Level (SAL) of $\leq 10^{-6}$, with an intended shelf life of two (2) years.

Biocompatibility Testing

The Sientra AlloX2 Pro Tissue Expanders are implantable devices. The contact category according to ISO 10993-1 is: Implant, tissue contacting, permanent (> 30 days). Where appropriate, testing was conducted according to methods prescribed by relevant ISO standards. All pre-established acceptance criteria were met.

Software Verification and Validation Testing

Not applicable. The subject device contains no software.

Electrical safety and electromagnetic compatibility (EMC)

Not applicable. The subject device contains no electric components, generates no electrical emissions, and uses no electrical energy of any type.

Bench Testing

Mechanical testing was conducted on the proposed AlloX2 Pro Tissue Expanders in order to demonstrate substantial equivalence with the predicate device. This testing was performed as required by the risk analysis and in accordance with design control procedures. All Testing was conducted in accordance with ASTM F1441-03, *Standard Specification for Soft-Tissue Expanders*. All mechanical performance testing results met their pre-determined acceptance criteria, demonstrating that the proposed device is substantially equivalent to the predicate device.

Magnetic Resonance Testing was performed per ASTM F2503-20 *Standard Practice for Marking Medical Devices and Other Items for Safety in the Magnetic Resonance Environment* as well as per FDA Guidance, *Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment* (May 2021), for a passive device. The Magnetic Resonance Testing results demonstrated that patients implanted with the AlloX2 Pro Tissue Expanders may safely undergo Magnetic Resonance Imaging under specific MR conditions per device labeling.

Animal Testing

Not applicable. Animal studies are not necessary to establish the substantial equivalence of this device.

Clinical Testing Summary [807.92(b)(2)]

Not applicable. Clinical data is not necessary to establish the substantial equivalence of this device.

Conclusions [807.92(b)(3)]

The collective performance testing demonstrates that the Sientra AlloX2 Pro Tissue Expander does not raise new questions of safety or effectiveness for its intended use when compared to the predicate device.

Results of the performance testing demonstrate that the Sientra AlloX2 Pro Tissue Expander met the predetermined acceptance criteria and is substantially equivalent to the predicate device.