November 10, 2019

Stryker ENT
Karen Peterson
Vice President, Clinical, Regulatory & Quality
3600 Holly Lane North, Suite 40
Plymouth, Minnesota 55447

Re: K192661
Trade/Device Name: LATERA Absorbable Nasal Implant System
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, Nose, And Throat Synthetic Polymer Material
Regulatory Class: Class II
Product Code: NHB
Dated: September 24, 2019
Received: September 25, 2019

Dear Karen Peterson:

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,

for Michael Ryan
Director
DHT1C: Division of ENT, Sleep Disordered Breathing, Respiratory and Anesthesia Devices
OHT1: Office of Ophthalmic, Anesthesia, Respiratory, ENT and Dental 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)*
K192661

Device Name
LATERA Absorbable Nasal Implant System

Indications for Use *(Describe)*
The LATERA Absorbable Nasal Implant System is indicated for supporting upper and lower lateral nasal cartilage.

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.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

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"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

510(k) Summary – K192661

Date Prepared:	November 7, 2019
Submitter Information:	Stryker ENT 3600 Holly Lane North, Suite 40 Plymouth, MN 55447
Establishment Registration:	3006345872
Contact Information:	Karen Peterson Vice President Clinical, Regulatory & Quality (763) 463-7066 karen.peterson@stryker.com
Device Information:	
Trade Name:	LATERA® Absorbable Nasal Implant System
Common Name:	Ear, Nose, Throat Synthetic Polymer Material
Classification Name:	Polymer, Ear, Nose and Throat, Synthetic, Absorbable
Product Code:	NHB
Classification:	Class II
Regulation Number:	21 CFR 874.3620
Predicate Device:	LATERA Absorbable Nasal Implant [K161191]

Device Description:
The LATERA Absorbable Nasal Implant System is intended to support upper and lower lateral cartilage in the nose. The system consists of the LATERA Absorbable Nasal Implant (Implant) and Delivery Device (Delivery Device). An Implant Positioning Guide is provided to serve as an external visual planning aid prior to Implant placement. The Implant is composed of a PLLA-PDLA copolymer that is predominantly cylindrical in shape with an approximate diameter of 1mm and lengths of 20mm and 24mm. The distal end of the Implant is forked to facilitate anchoring during implantation and the proximal end is narrower for increased flexibility. The disposable Delivery Device is comprised of a non-patient contacting handle assembly and a medical grade stainless steel 16-gauge delivery cannula. The Delivery Device enables placement of the Implant in a minimally invasive manner. Each Implant length (20mm, 24mm) is compatible with the Delivery Device packaged with the Implant. The LATERA Absorbable Nasal Implant System is provided sterile and is intended for single-use only.

Indication for Use:
The LATERA® Absorbable Nasal Implant System is indicated for supporting upper and lower lateral nasal cartilage.

Contraindications:
- Presence of an active infection at the implantation site.
- Patients known or suspected to have an allergy to PLA or absorbable materials.

Technological Characteristics:
The LATERA Absorbable Nasal Implant System (subject device) has the same indications for use and fundamental scientific technology as the predicate device LATERA Absorbable Nasal Implant System [K161191].

The subject device has the same technological characteristics (i.e., principle of operation, basic design, manufacture process, functionality, materials, biocompatibility, and sterile packaging) as the predicate device. The subject device adds an additional implant size (length of 20mm). Other changes made since the predicate clearance include modified implant geometry, extended shelf life, and modified sterilization process.

Substantial Equivalence:
The LATERA Absorbable Nasal Implant System has the same indications for use and fundamental scientific technology as the predicate device. LATERA Absorbable Nasal Implant System is substantially equivalent to the predicate device.

Performance Data:
Performance testing of the LATERA Absorbable Nasal Implant System consisted of design verification testing and distribution testing to support the additional implant size. Design verification testing, shelf life testing, and sterilization testing were completed to support the device modifications made since the predicate clearance. All testing passed and showed that the device meets design specifications and performed as intended.

Conclusion:
In conclusion, the indications for use and technological characteristics are the same as or equivalent to the predicate device. Performance testing has demonstrated that the device is as safe and as effective as the predicate device and that its performance is substantially equivalent to the predicate device.