February 12, 2020

Bioinspire Technologies, Incorporated
Margaret Dillon
2468 Embarcadero Way
Palo Alto, California 94303-3313

Re: K160101
Trade/Device Name: SinuBand
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal splint
Regulatory Class: Class I
Product Code: LYA

Dear Contact:

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. Specifically, FDA is assigning a new product code to replace the one listed on the original SE letter. FDA has created a new product code to better categorize your device technology. The new product code is as follows:

Product Code	Device Name
QJL	Splint, Intranasal Septal, CBER led

In addition, the procode QJL has been assigned to CBER. Like CDRH, CBER also has regulatory authority of certain medical devices and device led combination products. Assignment to CBER will better align this product with other products that include blood or cellular products. For questions regarding this letter please contact Sheryl Lard-Whiteford, Office of The Director, Center for Biologics Evaluation and Research, Food and Drug Administration, 240-402-7912, sherry.lard@fda.hhs.gov.

Sincerely,
Marjorie G. Shulman -S
Digitally signed by Marjorie G. Shulman -S
Date: 2020.02.12 08:30:43 -05'00'

Marjorie Shulman
Assistant Director, 510(k), De Novo, 513(g), Device Determinations and Custom Devices Team, Office of Regulatory Programs
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

July 27, 2016

BioInspire Technologies, Inc.
Ms. Margaret Dillon
Vice President, Regulatory Affairs and Quality
2468 Embarcadero Way
Palo Alto, CA 94303-3313

Re: K160101
Trade/Device Name: SinuBand
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: June 23, 2016
Received: June 27, 2016

Dear Ms. Dillon:

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,

Eric A. Mann -S

for Malvina B. Eydelman, M.D.
Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
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: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
K160101

Device Name
SinuBand

Indications for Use *(Describe)*
SinuBand is indicated for use in patients undergoing nasal/sinus surgery as a space-occupying dressing intended to separate mucosal surfaces and prevent formation of adhesions.

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.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"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."

BioInspire Technologies

K160101 - SinuBand 510(k) Summary

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the Safe Medical Devices Act (SMDA) of 1990 and Title 21 CFR Part 807.92(c).

I. SUBMITTER

BioInspire Technologies, Incorporated
2468 Embarcadero Way
Palo Alto, CA 94303
Phone: 707-239-5707
Fax: 707-239-5259
Contact Person: Margaret Dillon
mdillon@bioinspiretechnologies.com
Date Prepared: July 26, 2016

II. DEVICE

- Name of Device: SinuBand
- Common or Usual Name: Temporary Nasal Dressing
- Regulation Description: Intranasal Splint (21 CFR 874.4780)
- Regulatory Class: I
- Product Code: LYA

III. PREDICATE DEVICES

- MeroGel Nasal Dressing and Sinus Stent (K982731)
- AdvaCoat Gel and Stent (K070496)
- Synthemed Device (K082276)
- NasoPore Nasal Dressing (K052099)

IV. DEVICE DESCRIPTION

SinuBand is a sterile, single-use, bioresorbable two-layer film designed to be a temporary nasal dressing applied under endoscopic visualization after sinus surgery. SinuBand is composed of two layers, with one side designed to be placed against the nasal tissue and the other facing the nasal cavity.

V. INDICATIONS FOR USE

SinuBand is indicated for use in patients undergoing nasal/sinus surgery as a space-occupying dressing intended to separate mucosal surfaces and prevent formation of adhesions.

VI. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS WITH THE PREDICATE DEVICES

The SinuBand placement and method of action is the same as the predicate devices, using manual application to place the device in the nasal cavity after sinus/nasal surgery. The SinuBand and predicate devices are hygroscopic, forming a gelatinous mass when in contact with fluid and serving as mechanical/physical barrier which prevents adhesions from forming. The SinuBand and predicate devices separate the mucosal surfaces and perform as an adjunct to the healing process.

The SinuBand and predicate devices are resorbable within 14 days of placement. The SinuBand and predicate devices can be removed from the nasal cavity after endoscopic placement by gentle irrigation. Comparative testing of SinuBand and MeroGel Nasal Dressing and Sinus Stent was performed to demonstrate substantial equivalence.

Any differences in properties between the SinuBand and the identified predicate devices do not alter the intended use of the SinuBand nor affect the safety and effectiveness of the SinuBand relative to the predicate devices.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

Biocompatibility Testing

A biocompatibility evaluation for the patient-contacting materials of SinuBand was conducted in accordance with the International Standard ISO 10993-1 "Biological Evaluation of Medical Devices − Part 1: Evaluation and Testing within a Risk Management Process," as recognized by FDA. All test results were acceptable.

In Vitro Bench Testing

In vitro bench testing on SinuBand and the predicate device, MeroGel Nasal Dressing, evaluated mechanical and physical properties that are important to an effective nasal/sinus dressing, including: maximum sustained load, flexibility, ability to absorb water, pH, ease of placement and removal from tissue, and conformability. All test results were comparable for the two devices.

Animal Studies

Two (2) pre-clinical *in vivo* studies in a New Zealand white rabbit model of maxillary sinus surgery were completed as part of the evaluation of the SinuBand device. SinuBand was implanted in 16 intact or injured rabbit sinuses followed by histologic evaluation (hemorrhage, inflammation, fibrosis, bone remodeling, presence of device) of the sinus tissue for up to 28 days; 10 intact or injured rabbit sinuses that were not implanted served as controls. The results showed that the device rapidly adhered to the sinus mucosa and remained visible after 48 hours, but was no longer visible and appeared to be resorbed after 9-15 days. No significant histologic changes were identified when SinuBand was placed on intact mucosa (no injury), and the device did not alter inflammation, fibrosis or bone remodeling at injury sites. No complications were encountered during the study. The rabbit studies demonstrated the safety, biocompatibility and performance of SinuBand.

VIII. CONCLUSION

Testing on SinuBand has demonstrated the desired properties of a nasal/sinus dressing, including lack of toxicity, biocompatibility, and non-dislocation after application. In addition, comparative bench testing has established substantial equivalence of SinuBand to the predicate device, MeroGel Nasal Dressing and Sinus Stent, in several tests critical to the function of an effective nasal/sinus dressing, including maximum sustained load, flexibility, ability to absorb water, pH to support a wound healing environment, ease of placement and removal, and ability to conform to nasal anatomy. SinuBand and MeroGel also have a comparable residence time in the sinus cavity of approximately 2 weeks. The nonclinical and bench testing data demonstrate that SinuBand is substantially equivalent to MeroGel and the other identified predicate devices that are currently marketed for the same intended use.