DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

October 17, 2017

Chitogel, Ltd.
% Gregory Mathison
President
Regulatory Strategies, Inc.
3924 Cascade Beach Road
Lutsen, MN 55612

Re: K172179
Trade/Device Name: Chitogel Endoscopic Sinus Surgery Kit
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: July 10, 2017
Received: July 19, 2017

Dear Gregory Mathison:

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)*
K172179

Device Name
Chitogel Endoscopic Sinus Surgery Kit

Indications for Use *(Describe)*
The Chitogel Endoscopic Sinus Surgery Kit is indicated for use in patients undergoing nasal/sinus surgery as a space occupying packing to:
- Separate tissue or structures compromised by surgical trauma
- Separate and prevent adhesions between mucosal surfaces in the nasal cavity and minimize ostial stenosis following endoscopic sinus surgery
- Control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation
- Act as an adjunct to aid in the natural healing process

The Chitogel Endoscopic Sinus Surgery Kit is indicated for use as a nasal packing to treat epistaxis.

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 - K172179

This 510(k) summary information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92.

General Information

Applicant:	Chitogel Ltd 139 Moray Place Dunedin, 9016, New Zealand Tel: +64 21 969 149
Trade Name:	Chitogel Endoscopic Sinus Surgery Kit
Common Name:	Nasal packing
Classification Name:	Intranasal splint
Number:	21 CFR §874.4780
Device Classification:	Class I
Product Code:	LYA
Predicate Devices:	Novashield Injectable Nasal Packing and Stent (K141704)
Contact	Gregory Mathison US Agent T: 218.387.1559 E: gmathison@att.net
Date:	October 8, 2017

Substantially Equivalent to:

The Chitogel Endoscopic Sinus Surgery Kit is equivalent in intended use, principal of operation and technological characteristics to the Novashield Injectable Nasal Packing and Stent (K141704).

Description of the device subject to premarket notification

The Chitogel Endoscopic Sinus Surgery Kit consists of the following components:

- Sealed vial containing 300mg Dextran Aldehyde Powder
- Sealed vial containing 10ml Sodium Phosphate Buffer Solution
- Sealed vial containing 10ml Chitosan Succinaamide Solution
- 12cc control syringe
- Fluid dispensing connector
- Two (2) mixing cannulae
- Malleable cannula

The Chitogel Endoscopic Sinus Surgery Kit is used during nasal surgery. The components in the Chitogel Kit are mixed by the physician using the syringe and cannulae provided. The pre- measured components mix to form the biodegradable gel. Once the components are mixed and create the gel, the physician applies the gel to the target area using the malleable cannula and thereby creating a nasal packing.

All components are provide sterile and are for single use only.

Indications for Use

The Chitogel Endoscopic Sinus Surgery Kit is indicated for use in patients undergoing nasal/sinus surgery as a space occupying packing to:

- Separate tissue or structures compromised by surgical trauma
- Separate and prevent adhesions between mucosal surfaces in the nasal cavity and minimize ostial stenosis following endoscopic sinus surgery
- Control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation
- Act as an adjunct to aid in the natural healing process

The Chitogel Endoscopic Sinus Surgery Kit is indicated for use as a nasal packing to treat epistaxis.

Materials

The Chitogel Endoscopic Sinus Surgery Kit consists of well-known and commonly used materials. All materials are purchased from reputable vendors. Testing included the following:

- Cytotoxicity
- Sensitization
- Acute Systemic Toxicity

Animal Testing

Animal testing was conducted to assess the simulated clinical performance of the Chitogel Endoscopic Sinus Surgery Kit. The product was used per the product IFU – the individual components were mixed together forming the gel, the gel was injected into the sinus cavity via the nasal passage, the gel maintained its position in the sinus cavity and the gel was removed using saline irrigation. The simulated use of the Chitogel product in an animal model showed it could be combined into a gel, introduced into the sinus cavities, maintained position after introduction and degraded over time using saline irrigation. No adverse events were observed.

Journal articles:

Athanasiadis, T, Beule, B, Robinson, B, Robinson, S, Shi, Z, Wormald, PJ; *Effects of a Novel Chitosan Gel on Mucosal Wound Healing Following Endoscopic Sinus Surgery in a Sheep Model of Chronic Rhinosinusitis.* The Laryngoscope 118: June 2008

Clinical Experience

Several clinical studies involving the Chitogel product were completed. These randomized controlled studies were reported in published peer reviewed articles in scientific journals. The product was used per the product IFU and exhibited performance consistent with the indications for use. The Chitogel product was mixed into a gel and introduced into the sinus cavities via a cannula. Once in place, the following clinical observations were documented:

- The gel separated tissue or structures following surgery
- The gel separated and prevented adhesions between mucosal surfaces in the nasal cavity and minimized ostial stenosis following endoscopic sinus surgery
- The gel controlled minimal bleeding following surgery by a tamponade effect, blood absorption and platelet aggregation
- The gel acted as an adjunct to aid in the natural healing process

These observations were confirmed in the studies and submitted to and/or published in peer reviewed journals.

Journal articles:

Ha, T., Valentine, R., Moratti, S., Robinson, S., Hanton, L., Wormald, PJ; *A blinded randomized controlled trial evaluating the efficacy of Chitosan gel on ostial stenosis following endoscopic sinus surgery.* Submitted to International Forum of Allergy & Rhinology (IFAR)

Valentine, R., Athanasiadis, T., Moratti, S., Hanton, L., Robinson, S., Workald, PJ. *The efficacy of a novel chitosan gel on hemostatsis and wound healing after endoscopic sinus surgery.* American Journal of Allergy & Rhinology, January-February 2010 Vol.24 No. 1

Ha, T., Valentine, R., Moratti, S., Hanton, L., Robinson, S., Wormald, PJ. *The efficacy of a novel budesonide chitosan gel on wound healing following endoscopic sinus surgery.* Submitted to International Forum of Allergy & Rhinology (IFAR)

Non-Clinical Testing

Testing was conducted on sterile final product. Product testing followed the appropriate standards and guidance documents, with appropriate modifications following risk assessment. Testing plans were based upon FDA guidance documents and international standards. Testing was performed on baseline (non- aged) and aged products. Testing included:

- viscosity
- gel time
- delivery of gel
- biodegradation
- packaging

All samples passed testing and met the acceptance criteria of the specification.

Basis for Determination of Substantial Equivalence

Upon reviewing the safety information provided in this submission and comparing intended use, principle of operation and overall technological characteristics, the Chitogel Endoscopic Sinus Surgery Kit is determined to be substantially equivalent to existing legally marketed devices.

Comparison of Product Features

Trade name	Chitogel Endoscopic Sinus Surgery Kit	Novashield	SE Discussion
Product code	LYA	LYA	Same
510(k) number	K172179	K141704	
21CFR	874.4780	874.4780	Same
Device Classification	Class 1	Class 1	Same
Device Description	Chitosan based gel supplied in 3 components mixed into a gel by user	Chitosan based pre-mixed gel	Equivalent
Method of Operation	Gel injected into sinus cavity	Gel injected into sinus cavity	Equivalent

Intended Use	The Chitogel Endoscopic Sinus Surgery Kit is indicated for use in patients undergoing nasal/sinus surgery as a space occupying packing to: • Separate tissue or structures compromised by surgical trauma; • Separate and prevent adhesions between mucosal surfaces in the nasal cavity and minimize ostial stenosis following endoscopic sinus surgery • Control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation • Act as an adjunct to aid in the natural healing process The Chitogel Endoscopic Sinus Surgery Kit is indicated for use as a nasal packing to treat epistaxis.	NovaShield is indicated for use in patients undergoing nasal/sinus surgery as a space occupying packing to: • Separate tissue or structures compromised by surgical trauma; • Separate and prevent adhesions between mucosal surfaces in the nasal cavity; • Control minimal bleeding following surgery or trauma by tamponade effect, blood absorption and platelet aggregation • Act as an adjunct to aid in the natural healing process NovaShield is indicated for use as a nasal packing to treat epistaxis.	Equivalent
Components	Dextran Aldehyde Powder Sodium Phosphate Buffer Solution Chitosan Succinamide Solution	Chitosan Cellulose	Equivalent
Sterilization	Supplied sterile - ETO & Gamma	Supplied sterile – unknown method	Equivalent
Single use	Yes	Yes	Equivalent
Shelf life	3 months	Unknown	Equivalent
Packaging	Tyvex / poly header pouch	Unknown	Industry standard packaging
Materials	Chitosan based gel	Chitosan based gel	Equivalent
Biodegradable	Yes	Yes	Equivalent
Published Clinical Data	Yes	No	Equivalent – even though the predicate device does not have any published clinical data, both products have the same intended use and clinical application

Conclusion

The products are substantially equivalent as the indications for use, clinical application and materials are equivalent to existing legally marketed predicate products.