March 22, 2023

BioMed ENT, Inc.
% Marcela Garcia
Principal Investigator
BioMed Elements B.V.
Kerkenbos 1077-V
Nijmegen, Gelderland 6546 BB
Netherlands

Re: K230142
Trade/Device Name: Epi-Stop Nasal Gel/Epistaxis Pack
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal Splint
Regulatory Class: Class I
Product Code: LYA
Dated: January 18, 2023
Received: January 18, 2023

Dear Marcela Garcia:

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,

Joyce C. Lin -S

for Shu-Chen Peng, Ph.D.
Assistant Director
DHT1B: Division of Dental and
ENT 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: 06/30/2023
See PRA Statement below.

510(k) Number *(if known)*
K230142

Device Name
Epi-Stop™ Nasal Gel/Epistaxis Pack

Indications for Use *(Describe)*
Epi-Stop™ Nasal Gel/Epistaxis Pack is a sterile, single use device indicated for use in patients suffering from anterior epistaxis to:
- Help control minimal bleeding following trauma by barrier function, blood absorption and platelet aggregation;
- Act as an adjunct to aid in the natural healing process.

Epi-Stop™ Nasal Gel/Epistaxis Pack is indicated for use as a nasal packing to treat anterior epistaxis.
Epi-Stop™ Nasal Gel/Epistaxis Pack is intended for use under the direction of a licensed healthcare provider.

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.

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510(K) SUMMARY

In accordance with the Food and Drug Administration Rule to implement provisions of the Safe Medical Devices Act of 1990 and in conformance with 21 CFR 807.92, this information serves as a Summary of Safety and Effectiveness for the use of Epi-Stop™ Nasal Gel/Epistaxis Pack.

Applicant:	BioMed ENT, Inc. 18911 Hardy Oak Blvd, San Antonio, TX 78258, United States, 210-846-0692
Trade name:	Epi-Stop™ Nasal Gel/Epistaxis Pack
Common name:	Nasal Packing
Classification name:	Intranasal Splint
Number:	21 CFR 874.4780
Device Classification:	Class I
Device Product Code:	LYA
Device Panel:	Ear, Nose and Throat
Predicate Device:	Chitogel® Endoscopic Sinus Surgery Kit (K172179)
Contact Person:	Tonny Voermans President T: +31(0) 24 711 4079 E: t.voermans@biomed-ent.com
Date:	2023 March 21

Device Description

Epi-Stop™ Nasal Gel/Epistaxis Pack is a single use, hemostatic, and injectable gel, made of crosslinked gelatin and hyaluronic acid, indicated for the treatment of anterior epistaxis. Epi-Stop™ Nasal Gel/Epistaxis Pack creates a moist environment for healing and the ability of absorbing and stopping nose bleeding within minutes. Due to its viscoelasticity and low extrusion force, Epi-Stop™ Nasal Gel/Epistaxis Pack can be injected into the anterior nasal cavity and the gel must be left in the nose for at least 72 hours. Afterwards, the gel can be

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removed by using safe water for gentle irrigation (either sterile or boiled water) or using safe lukewarm water.

Principle of operation. In Figure 1 the commercial presentation of Epi-Stop™ Nasal Gel/Epistaxis Pack is shown and it consists of a cardboard box (secondary package) as an outer package (a). Inside the box, a leaflet with the instructions for use (IFU) can be found, together with a sterile sealed-pouch (primary package) containing a capped syringe and an applicator (b). The sterile pouch can be peeled-open, and the capped syringe and applicator can be taken out of the primary package (c). The gel is contained and sealed in this syringe and should only be injected through the applicator by a medical professional or trained personnel. To properly use Epi-Stop™ Nasal Gel/Epistaxis Pack, a medical professional or trained personnel should twist-and-remove the cap tip from the syringe (d) and attach the applicator instead (e). The applicator can then be introduced in the anterior nasal cavity against the injury site, and the gel can be injected in one smooth notion in compliance with the IFU.

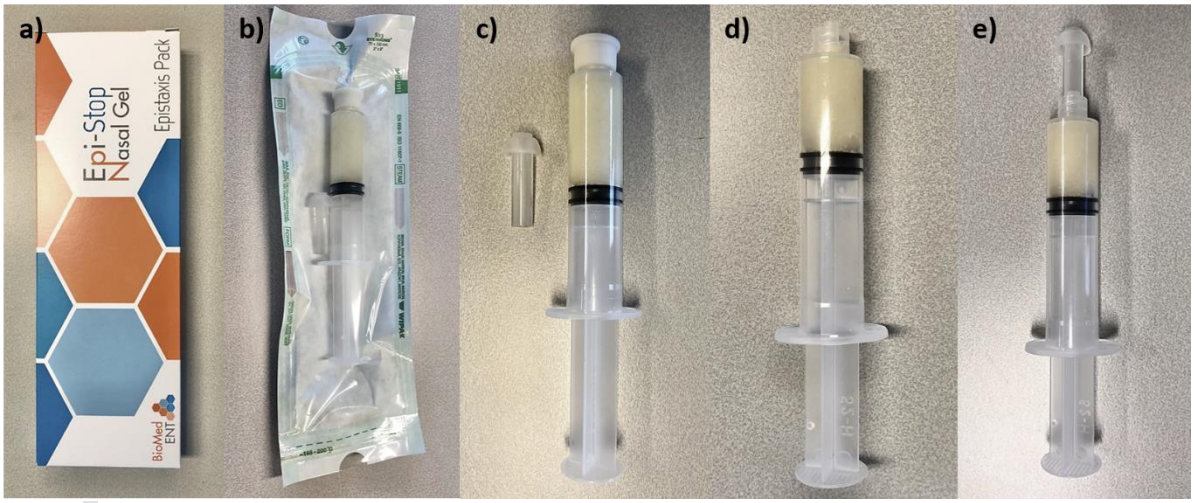

Figure 1. Visual representation of Epi-Stop™ Nasal Gel/Epistaxis Pack and its key components.

Mechanism of Action. Briefly, to successfully stop anterior mild bleeding, Epi-Stop™ Nasal Gel/Epistaxis Pack relies primarily on an optimal occlusion, followed by good absorption to retain blood, and lastly on an optimal viscosity designed to facilitate the subject device's ability to properly adapt to the implant area once it has been injected in the anterior nasal cavity.

Device components. A brief summary in Table 1 of the product components with the duration and type of contact.

Table 1. This table contains a list of all product components of Epi-Stop™ Nasal Gel/Epistaxis Pack, together with duration and type of contact for each of the items listed.

	Device components	Type of contact	Duration
1	Cardboard box	Not a patient–contacting material	N/A
2	IFU	Not a patient–contacting material	N/A
3	Pouch	Not a patient–contacting material	N/A
4	Cap tip	Not a patient–contacting material	N/A
5	Syringe	patient–contacting material.	< 1 minute
6	Applicator[1]	patient–contacting material.	< 1 minute
7	Epi-Stop™ Nasal Gel	patient–contacting material.	72 hours

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Indications for use

Epi-Stop™ Nasal Gel/Epistaxis Pack is a sterile, single use device indicated for use in patients suffering from anterior epistaxis to:

- Help control minimal bleeding following trauma by barrier function, blood absorption and platelet aggregation;
- Act as an adjunct to aid in the natural healing process.

Epi-Stop™ Nasal Gel/Epistaxis Pack is indicated for use as a nasal packing to treat anterior epistaxis.

Epi-Stop™ Nasal Gel/Epistaxis Pack is intended for use under the direction of a licensed healthcare provider.

Contraindications:

This product is contraindicated for use in patients with a known hypersensitivity/allergy to porcine-derived gelatin or its derivatives.

Possible Adverse Reactions:

Possible adverse effects associated with product use can include Allergic reactions, Scarring/synechia and Toxic shock syndrome (rare). For more information, please read Warnings and Precautions section in the Instructions For Use.

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Comparison of Technological Characteristics with the Predicate Device.

Table 2. Comparison of predicate device with subject device Epi-Stop™ Nasal Gel/Epistaxis Pack

	Subject device	**Predicate device**
	K230142 Epi-Stop™ Nasal Gel/Epistaxis Pack **BioMed ENT, Inc.**	**K172179** Chitogel® Endoscopic Sinus Surgery Kit **Chitogel Ltd**
Product Codes	LYA	LYA,
Regulations	874.4780	874.4780,
Device Classification	Class I	Class I
Indications for use	**Indications for use:** Epi-Stop™ Nasal Gel/Epistaxis Pack is a sterile, single use device indicated for use in patients suffering from anterior epistaxis to: - Help control minimal bleeding following trauma by barrier function, blood absorption and platelet aggregation; - Act as an adjunct to aid in the natural healing process. Epi-Stop™ Nasal Gel/Epistaxis Pack is indicated for use as a nasal packing to treat anterior epistaxis. Epi-Stop™ Nasal Gel/Epistaxis Pack is intended for use under the direction of a licensed healthcare provider.	**Indications for use:** 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. - 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.
Technological Characteristics	Injectable Nasal Gel	Injectable Nasal Gel

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	Subject device	Predicate device
How supplied	Epi-Stop™ Nasal Gel/Epistaxis Pack is a single use, injectable gel, supplied sterile. Epi-Stop™ Nasal Gel/Epistaxis Pack consists of a pre-filled syringe containing the gel, and an attachment/applicator to help deliver the gel in the Kiesselbach's plexus.	Chitogel® Endoscopic Sinus Surgery Kit is a single use, injectable gel, supplied sterile. In Chitogel® Endoscopic Sinus Surgery Kit all components of the gel need to be mixed on-site by the physician, using the syringe and the attachment provided. The pre-measured components mix to form the biodegradable gel.
Materials	-Porcine-derived gelatin (derived from collagen) and -Hyaluronic acid and -Phosphate Buffer solution	- Chitosan and - Dextran Aldehyde Powder and - Phosphate Buffer Solution
Method of Action/Removal	**Method of Action.** Gel injected in the anterior nasal cavity. **Removal.** Epi-Stop™ Nasal Gel/Epistaxis Pack can be removed by using safe water for gentle irrigation (either sterile or boiled water) or using safe lukewarm water.	**Method of Action.** Gel injected in the sinus cavity **Removal.** Chitogel® Endoscopic Sinus Surgery Kit is eliminated via gentle irrigation using saline or water.
Sterilization	Supplied sterile - Steam sterilization	Supplied sterile - ETO & Gamma
Sterilization Assurance Level	10^{-6} SAL	10^{-6} SAL
Single Use	Yes	Yes
Shelf life	18 months	3 months
Biocompatibility	Complies with ISO 10993-1	Complies with ISO 10993-1

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Biocompatibility testing

The Epi-Stop™ Nasal Gel/Epistaxis Pack consists of well-known and commonly used materials. All materials are purchased from reputable vendors, and Epi-Stop™ Nasal Gel/Epistaxis Pack has been evaluated under biocompatibility studies, and have successfully passed all of the following:

Cytotoxicity. A Cytotoxicity study was conducted to analyze if Epi-Stop™ Nasal Gel/Epistaxis Pack could cause cell damage or cell death. Thus, the cytotoxic effect of Epi-Stop™ Nasal Gel/Epistaxis Pack was investigated through a Cytotoxic-Direct Contact test in compliance with ISO 10993-5:2009 and the standards of Good Laboratory Practice. According to the results and acceptance criteria stated in ISO 10993-5:2009, the test item Epi-Stop™ Nasal Gel/Epistaxis Pack must be considered **NOT CYTOTOXIC**.

Sensitization. A sensitization study was conducted to investigate if Epi-Stop™ Nasal Gel/Epistaxis Pack could induce an abnormally sensitive reaction on skin. Thus, Epi-Stop™ Nasal Gel/Epistaxis Pack was submitted to a biological evaluation in order to identify its potential sensitizing effects; this was done through a Delayed Hypersensitivity test (GPMT test) in compliance with ISO 10993-10:2010 and the standards of Good Laboratory Practice. To summarize, on the basis of the results, interpreted according to ISO 10993-10:2010, the test item Epi-Stop™ Nasal Gel/Epistaxis Pack must be considered **NOT SENSITIZING.**

In Vivo Acute Skin Irritation. An in vivo acute skin irritation test was conducted to investigate if Epi-Stop™ Nasal Gel/Epistaxis Pack could cause an irritant effect on skin. Thus, a biological evaluation was performed on Epi-Stop™ Nasal Gel/Epistaxis Pack via the following test: Skin Irritation in compliance with ISO 10993-23:2021 and the standards of Good Laboratory Practice. To summarize, on the basis of the results, interpreted according to ISO 10993-23:2021, the test item Epi-Stop™ Nasal Gel/Epistaxis Pack must be considered **Negligibly** irritant for the skin.

Acute Systemic Toxicity. An acute systemic toxicity test was conducted to investigate if Epi-Stop™ Nasal Gel/Epistaxis Pack could induce any adverse or toxic effect following it's placement. Thus, a biological evaluation was conducted on Epi-Stop™ Nasal Gel/Epistaxis Pack via a Systemic Toxicity test in compliance with ISO 10993-11:2017 and the standards of Good Laboratory Practice. In summary, and based on the results, which were interpreted in accordance with ISO 10993-11:2017, the test sample Epi-Stop™ Nasal Gel/Epistaxis Pack **does not cause toxic symptoms** and **satisfies** with the requirements of the test.

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Test	Applicable standards	Status
Cytotoxic-Direct Contact test	ISO 10993-5:2009 Good Laboratory Practice	Not cytotoxic
Sensitization	ISO 10993-10:2010 Good Laboratory Practice	Not sensitizing
In Vivo Acute Skin Irritation	ISO 10993-23:2021 Good Laboratory Practice	Not irritant
Acute Systemic Toxicity	ISO 10993-11:2017 Good Laboratory Practice	Not toxic

All Biocompatibility studies mentioned above were conducted in compliance with the following standards of Good Laboratory Practice:

- OECD Series on Principles of Good Laboratory Practice and Compliance Monitoring – OECD principles of Good Laboratory Practice (as revised in 1997) – Environment Directorate – Organization for Economic Co- Operation and Development, Paris 1998.
- Legislative decree n. 50 of March the 2nd, 2007. Enforcement of Community Directives 2004/9/CE and 2004/10/CE, concerning the inspection and verification of Good Laboratory Practice and the drawing of the legislative, regulatory and administrative dispositions relative to the application of Good Laboratory Practice rules, to the control of their application on the assays performed on the chemical substances (GU n.86 of April the 13th, 2007).
- United States Food and Drug Administration, Title 21 Code of Federal Regulations Part 58, Federal Register 22 December 1978, and subsequent amendments.
- GLP Certification n. 2019/25 released by the Italian Ministry of Health on September 12th 2019 authorizing Eurofins Biolab S.r.l. to perform analyses in compliance with the principles of good laboratory practices.

Performance testing

Performance of Epi-Stop™ Nasal Gel/Epistaxis Pack was analyzed and evaluated together with the predicate device Chitogel® Endoscopic Sinus Surgery Kit. In summary, absorption, occlusion, dynamic viscosity, extrusion force, and pH were the five tests conducted.

Occlusion.

Occlusion of the injury site is an important property responsible for the sealing between the wound's edges and the gel surface. A good occlusion will allow the hemostat to stop any leakage or outflow of blood outside the perimeter of the wound. The occlusion property of Epi-Stop™ Nasal Gel/Epistaxis Pack's was

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tested in comparison with Chitogel® Endoscopic Sinus Surgery Kit. Briefly, in summary to the occlusion results, there was no leakage of water seen in any of the devices tested for a period of 60 minutes. Both, the predicate and subject device succeeded in sealing the open surface of the glass flask, preventing the water from leaking outside the flask containers.

Absorption.
The absorption property of an hemostat is relevant in allowing the retention of blood while the body carries on, independently, with its coagulation process. To test the retention that the Gelatin-HA meshwork can provide to Epi-Stop™ Nasal Gel/Epistaxis Pack an absorption test was conducted in comparison with Chitogel® Endoscopic Sinus Surgery Kit. In summary to the absorption results, it was concluded that both, the predicate device and subject device performed highly similar regarding the absorption property. After three hours of being submerged in water, both devices showed a comparable absorbance of water, based on their initial weight.

Dynamic Viscosity.
The internal resistance of Epi-Stop™ Nasal Gel/Epistaxis Pack is an important characteristic as it reflects upon the force or pressure required to spread the gel. Once adhered to the edges of the wound, Epi-Stop™ Nasal Gel/Epistaxis Pack will adapt to the surrounding areas to render the device more comfortable upon placement. For this, the internal resistance of Epi-Stop™ Nasal Gel/Epistaxis Pack was measured and compared to Chitogel® Endoscopic Sinus Surgery Kit. In summary, both Epi-Stop™ Nasal Gel/Epistaxis Pack and Chitogel® Endoscopic Sinus Surgery Kit showed viscosities within the acceptable range for a hemostat. However, although the viscosity of Epi-Stop™ Nasal Gel/Epistaxis Pack is lower than that of Chitogel® Endoscopic Sinus Surgery Kit, it will not compromise its intended use, but rather only improves the handling characteristics with respect to injectability and adaptability to the surrounding implant area. The different viscosity levels seen in the subject device (when compared to the predicate) are primarily intended to support the handling properties of the device. This in mind, to successfully stop anterior minimal bleeding, Epi-Stop™ Nasal Gel/Epistaxis Pack relies primarily on an optimal occlusion, followed by good absorption to retain blood, and lastly on an optimal viscosity designed to facilitate the subject device's ability to properly adapt to the implant area once it has been injected in the anterior nasal cavity.

Extrusion Force.
The applied force needed in order to eject the gel from the syringe was also analyzed in both devices. It was expected that both gels should be extruded from its own syringe by using similar extrusion force. Both devices scored within the acceptance range.

pH.

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To help establish the stability of Epi-Stop™ Nasal Gel/Epistaxis Pack over the entirety of its shelf life, the pH has been measured so far at 0, 3.5, and 18 months real-time. In summary, the pH of Epi-Stop™ Nasal Gel/Epistaxis Pack remained stable for the entirety of the proposed shelf-life, 18 months.

In-vivo study.
To verify that Epi-Stop™ Nasal Gel/Epistaxis Pack stays at the initial site of placement (bleeding site) for a period of three (3) days, and to test the hemostatic capabilities of the device, an in vivo animal study was conducted. Chitogel® Endoscopic Sinus Surgery Kit was included in this study as it is the predicate device that Epi-Stop™ is claiming substantial equivalence to.

In conclusion, both Epi-Stop™ Nasal Gel/Epistaxis Pack and Chitogel® Endoscopic Sinus Surgery Kit were able to stop anterior mild bleeding within the timeframe indicated. Although the predicate was slightly faster, both devices performed within the same acceptance criteria range. Together with this, according to the observations from the study, both gels also remained at the injection site and no dripping was observed during 24, 48, and 72 hours of monitoring.

Conclusion

In conclusion, Chitogel® Endoscopic Sinus Surgery Kit and Epi-Stop™ Nasal Gel/Epistaxis Pack are considered substantially equivalent since both devices are single use, and injectable gels that are provided sterile for the treatment of anterior epistaxis. These devices are also made of biopolymers recognized for their mucoadhesive properties (i.e. chitosan or gelatin). Both devices are indicated for use as a nasal packing to treat anterior epistaxis, and supplied sterile with a SAL of 10^{-6}. Both, the predicate and subject device were tested through biocompatibility analyses and both, Chitogel® Endoscopic Sinus Surgery Kit and Epi-Stop™ Nasal Gel/Epistaxis Pack, passed Cytotoxicity, Sensitization, and Acute Systemic Toxicity. In addition to this, Epi-Stop™ Nasal Gel/Epistaxis Pack also passed *in vivo* skin irritation test.

The differences between the predicate and subject device are not significant enough to compromise the safety and effective performance of Epi-Stop™ Nasal Gel/Epistaxis Pack since it shares the same characteristics as Chitogel® Endoscopic Sinus Surgery Kit in order to effectively treat anterior epistaxis. Epi-Stop™ Nasal Gel/Epistaxis Pack also shares almost identical indications for use, highly similar technology (e.g., both are single use gels delivered in syringes), and mode of removal with regards to the predicate device discussed above.

To finalize, performance between devices was compared by testing properties such as absorption, occlusion, dynamic viscosity, extrusion force, and pH. Hence, Chitogel® Endoscopic Sinus Surgery Kit and Epi-Stop™ Nasal

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Gel/Epistaxis Pack were analyzed and both devices exhibited values within acceptable ranges. Moreover, the in vivo study performed in both, the subject and predicate also showed that both devices remain at the injection site and are capable of stopping anterior bleeding in less than a minute. Based on these data, it was concluded that Epi-Stop™ Nasal Gel/Epistaxis Pack is as safe and effective as Chitogel® Endoscopic Sinus Surgery Kit when it comes to the treatment of anterior epistaxis.