December 8, 2020

Medtronic Xomed
Matthew Harmon
Principal Regulatory Specialist
6743 Southpoint Drive North
Jacksonville, Florida 32256

Re: K202623
Trade/Device Name: Novapak Nasal Sinus Packing and Stent
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal splint
Regulatory Class: Class I
Product Code: LYA
Dated: September 9, 2020
Received: September 10, 2020

Dear Matthew Harmon:

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 Malvina B. Eydelman, M.D.
Director
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)*

K202623

Device Name
Novapak™ Nasal Sinus Packing and Stent

Indications for Use *(Describe)*
The Novapak Nasal Sinus Packing and Stent is intended 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.

Novapak 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 – K202623

Company: Medtronic Xomed, Inc.
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Contact: Matthew Harmon
Principal Regulatory Affairs Specialist
Phone: (904) 332-6704
E-mail: matthew.harmon@medtronic.com

Device Trade name: Novapak™ Nasal Sinus Packing and Stent

Common Name: Intranasal Packing and Stent, Intranasal Splint

Classification Name: Intranasal Splint (21 CFR 874.4780)

Classification: Class I Non-exempt (21 CFR 874.4780)

Product Code: LYA

Predicate Device:	NasoPore®	K052099
Reference Devices:	Posisep®	K122494
	Novashield™	K141704
	Chitogel™	K172179

Device Description:

Novapak™ is a single use, nasal packing and stent for use following sinus surgery to prevent adhesions, control mild bleeding and provide a level of antibacterial effectiveness. Novapak™ is composed of formulated chitosan and cellulose ingredients in a sponge form. The sponge can be compressed for insertion into anatomy and can be cut to size.

Novapak™ hydrates with sterile saline and forms a gel. The sponge dissolves within the nasal cavity with daily irrigation and natural mucus flow over several days. Residence time is typically 7-14 days with adequate irrigation. Alternately, the dressing may be removed through gentle aspiration at the discretion of the physician.

Indications for Use:

Novapak™ Nasal Sinus Packing and Stent 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.

Novapak™ Nasal Sinus Packing and Stent is indicated for use as a nasal packing to treat epistaxis.

Substantial Equivalence:

Novapak™ Nasal Sinus Packing and Stent is substantially equivalent in intended use and performance characteristics to NasoPore®, 510 (k) Number K052099, clearance date 11/21/2005.

The differences between the indications for the subject device Novapak™ and Nasopore® are not critical to the intended use of the device, and do not affect the safety and effectiveness of the subject device when used as labeled. Both the subject and predicate devices are indicated to separate and prevent adhesions between mucosal surfaces in the nasal cavity, and to control minimal bleeding following surgery or nasal trauma by the tamponade effect and blood absorption.

The subject device Novapak™ has some indications in addition to those for Nasopore®. These indications include separating structures compromised by surgical trauma, controlling minimal bleeding by platelet aggregation, and use as a nasal packing to treat epistaxis. These indications are matched by those in two reference devices Posisep™, Novashield™, and Chitogel.

Novapak™ and Nasopore® have different technological characteristics. They are made from different materials. The subject device Novapak™ is made of a combination of cellulose and chitosan, while the predicate Nasopore® is made of fragmentable poly (DL-Lactide-co-e-caprolactone) urethane. Performance testing (described below) shows that the subject device Novapak™ performs equivalently to the predicate device Nasopore®.

Biocompatibility:

Biocompatibility testing was performed using ISO 10993 Biological Evaluation of Medical Devices and FDA guidance document “Use of International Standard ISO 10993-1, ‘Biological evaluation of medical devices – Part 1: Evaluation and testing within a risk management process,’” issued June 16, 2016. The Novapak™ Nasal Sinus Packing and Stent complies with the biocompatibility requirements for its intended use.

Sterilization:

The Novapak™ Nasal Sinus Packing and Stent is sterilized using an e-beam radiation dose of 20-30kGy validated to deliver a minimum sterility assurance level (SAL) of 10^6.

Performance Testing:

Performance testing was conducted on the 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:

- Absorption and hydration testing (both saline and blood)
- Degradation and compression testing.
- Hemolysis and platelet activation testing.
- Bacterial Log Reduction Testing
- Bacterial barrier testing

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

Shelf Life and Packaging Integrity Testing:

Shelf life testing was performed on the sterile final product and its packaging according to the applicable standards and guidance documents. The packaging was subjected to both accelerated and real-time aging. The sterile final product was subjected to real-time aging. The packaging was also subjected to packaging integrity testing, including testing after transportation simulation, high altitude testing, and environmental conditioning.

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

Antibacterial Information:

The antibacterial effectiveness of Novapak™ was tested against the following bacterial strains. The table below outlines the timeframe in which Novapak™ demonstrated antibacterial activity to the tested bacterial strain. Note: *in vitro* efficacy is not correlated to clinical effectiveness.

Bacterial Strain	ATCC	24 hours	48 hours	3 days	7 days
Pseudomonas aeruginosa	9027	→	→	→	→
Staphylococcus aureus	25923	→	→	→	→
Staphylococcus epidermidis	12228	→	→	→	→
Escherichia coli	8739	→	→	→	→
Citrobacter freundii	8090	→	→	→	→
Enterobacter aerogenes	13048	→	→	→	→

Klebsiella pneumonia	4352				
Proteus mirabilis	4630				
Serratia marcescens	13880				
Haemophilus influenzae	53782				
Moraxella catarrhalis	8193				
Staphylococcus aureus (MRSA)	33591				
Staphylococcus saprophyticus	15305				
Micrococcus luteus	49732				
Streptococcus mutans	25175				
Streptococcus pneumoniae	10015				
Corynebacterium diphtheriae	296				
Corynebacterium tuberculostearicum	35693				

The Novapak Nasal Sinus and Stent was also tested as a bacterial barrier. The testing shows that the Novapak Nasal Sinus and Stent acts as a protective barrier by preventing bacterial growth through the hydrated Novapak sponge for a 72 hour period.

Conclusion:

Utilizing FDA's Guidance for Industry and FDA Staff "Format for Traditional and Abbreviated 510(k)s" issued on September 13, 2019, a comparison of key characteristics demonstrates that the proposed device Novapak™ Nasal Sinus Packing and Stent is substantially equivalent to the predicate device in terms of performance characteristics. The Novapak™ Nasal Sinus Packing and Stent is as safe, as effective, and performs as well as the predicate device.