K113585

APR 25 2012

Section 5 – 510(k) Summary or 510(k) Statement

I. General Information

Submitter: CogENT Therapeutics, LLC
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Hayward, CA 94544
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Contact Person: Glen Gong
Principal
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Summary Preparation Date: April 3, 2012

II. Names

Device Names: Nasal/Epistaxis Pack

Primary Classification Names: Intranasal splint, ENT polymer material, and Epistaxis (packing)

III. Predicate Devices

- Nasopore® manufactured by Polyganics BV (K052099)
- Sepragel ENT Bioresorbable Packing/Stent manufactured by Genzyme Corporation (K043035)
- Rhinocell® Nasal Packings manufactured by Boston Medical Products, Inc. (K972459)
- MeroPack Bioresorbable Nasal Packing and Sinus Stent manufactured by Medtronic Xomed Inc. (K041381)
- MeroGel™ Control Gel ENT Surgical Dressing manufactured by Medtronic Xomed Inc. (K002972)

IV. Product Description

The Nasal/Epistaxis Pack is a sterile, single use, co-polymer of polyethylene glycol (PEG) and chitosan provided as a dry 4.0 cm x 2.4 cm x 0.3 cm pack. Upon placement, the Nasal/Epistaxis Pack absorbs fluids in the field and swells and conforms to the mucosal tissue/treatment site surfaces to separate tissues and prevent adhesions, control minimal bleeding following surgery or trauma, to treat epistaxis, and to act as an adjunct to aid in the natural healing process.

V. Indications for Use

The Nasal/Epistaxis Pack is a sterile, single use device intended for use in patients undergoing nasal/sinus surgery as a space-occupying packing.

The Nasal/Epistaxis Pack 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 during mesothelial cell regeneration in the nasal cavity;
- Help control minimal bleeding following surgery or trauma;
- Help control minimal bleeding following surgery or nasal trauma by tamponade effect, blood absorption and platelet aggregation; and
- Act as an adjunct to aid in the natural healing process.

The Nasal/Epistaxis Pack is indicated for use as a nasal packing to treat epistaxis.

VI. Rationale for Substantial Equivalence

The Nasal/Epistaxis Pack shares the same indications for use, device operation, overall technical and functional capabilities, and therefore is substantially equivalent to the predicate devices for use as a space-occupying stent/packing for nasal/sinus use.

In addition, comparative performance test data demonstrated adequate device performance.

VII. Safety and Effectiveness Information

The review of the indications for use and technical characteristics provided demonstrates that the Nasal/Epistaxis Pack is substantially equivalent to the predicate devices (see Table on following page).

VIII. Conclusion

The Nasal/Epistaxis Pack was found to be substantially equivalent to the predicate devices.

The Nasal/Epistaxis Pack shares identical indications for use, similar design features, and functional features with, and thus is substantially equivalent to, the predicate devices.

Comparison of the Nasal/Epistaxis Pack and the Predicate Devices

Devices → / Characteristic ↓	**K11_____** Nasal/Epistaxis Pack **CogENT Therapeutics**	**K052099** Nasopore® **Polyganics BV**	**K043035** Sepragel ENT Bioresorbable Packing/Stent **Genzyme Corp.**	**K972459** Rhinocell® Nasal Packings **Boston Medical Products, Inc.**	**K041381** MeroPack Bioresorbable Nasal Packing and Sinus Stent **Medtronic Xomed Inc.**	**K002972** MeroGel™ Control Gel ENT Surgical Dressing **Medtronic Xomed Inc.**
Product Codes	LYA = Intranasal splint EMX = Epistaxis balloon KHJ = ENT Synth. Polymer	LYA = Intranasal splint	KHJ = ENT Synthetic Polymer Material	EMX = Epistaxis balloon	LYA = Intranasal Splint	KHJ = ENT Synthetic Polymer Material
Regulations	874.4780 Intranasal splint; 874.4100 Epistaxis balloon 874.3620 ENT Polymer	21 CFR 874.4780	21 CFR 874.3620	21 CFR 874.4100	21 CFR 874.4780	21 CFR 874.3620
Indications for Use	See Section V above	See Section V above				
Ingredients	Crosslinked Polyethylene Glycol (PEG) and Chitosan	Fragmentable poly(DL-lactide-co-ε-caprolactone) urethane	Derivative of hyaluronic acid	Polyvinyl alcohol (PVA) sponge using a patented formula.	Esterfied hyaluronic acid (HYAFF®) and Collagen	Esterfied hyaluronic acid (HYAFF®)
Method of Action/ Removal	• Hygroscopic, forms gelatinous mass in contact w/ fluids • Natural elimination. aspiration or gentle irrigation of residues • Upon application device swells and conforms to mucosal surfaces.	• Hygroscopic, fragments in contact with fluids • Fragments within several days after insertion in the nasal cavity • Drained from the nasal cavity via the natural mucus flow.	• Fills nasal/sinus cavities • Leaves placement site by natural elimination, or may be aspirated from the cavity earlier at physician's discretion	• The packings will expand as fluid is introduced, giving the surgeon time for accurate positioning.	• Hygroscopic, forms gelatinous mass in contact with fluids. • Absorbent >10 times weight of device • The stent gradually degrades over time and is slowly absorbed within 14 days, or it may be aspirated from the cavity earlier at the discretion of the physician.	• Hygroscopic, forms gelatinous mass in contact with fluids. • Absorbent >6 times weight of device • Dressing may be compressed/ shaped by surgeon as needed • Gel eventually dissolves, or it may be aspirated from the cavity earlier at the discretion of the physician.
Sterility	Sterile by E-Beam Irradiation	Sterile by EO gas	Sterile	Sterile by Gamma Irradiation	Sterile by Gamma Irradiation	Sterile by Gamma Irradiation
Biocompat	Complies with ISO 10993-1	Complies with ISO 10993-1	Unknown – not specified	Unknown – not specified	Complies with ISO 10993-1	Complies with ISO 10993-1
How Supplied	• 4.0 cm x 2.4 cm x 0.3 cm pack • Single use • Single barrier Foil pouch • Sterile, ready to use	• Single use • Single barrier Tyvek pouch	• Single use • Transparent viscoelastic gel	• Variety of shapes and sizes to choose from, both with and without integral airways • Sterile, ready to use	• Single use • Lyophilized (freeze dried) and compressed dressing	• Single use

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Room –WO66-G609
Silver Spring, MD 20993-0002

CogENT Therapeutics, LLC
% Ms. Anne Worden
Regulatory Consultant
703 Sandoval Way
Hayward, CA 94544

APR 25 2012

Re: K113585
Trade Name: Nasal/Epistaxis Pack
Regulation Number: 21 CFR 874.4780
Regulation Name: Intranasal splint
Regulatory Class: I
Product Code: LYA, EMX
Dated: April 3 2012
Received: April 4, 2012

Dear Ms. Worden:

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 go to http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR 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 Small Manufacturers, International and Consumer Assistance 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,

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

K113585

Indications for Use Statement

510(k) Number (if known): **K11**

Device Name: **Nasal/Epistaxis Pack**

Indications for Use:

The Nasal/Epistaxis Pack is a sterile, single use device intended for use in patients undergoing nasal/sinus surgery as a space-occupying packing.

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- Help control minimal bleeding following surgery or trauma;
- Help control minimal bleeding following surgery or nasal trauma by tamponade effect, blood absorption and platelet aggregation;
- Act as an adjunct to aid in the natural healing process.

The Nasal/Epistaxis Pack is indicated for use as a nasal packing to treat epistaxis.

Prescription Use ✓ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Ophthalmic, Neurological and Ear,
Nose and Throat Devices

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