K051911

DEC 6 2005

Section 8.0

510(k) Summary of Safety and Effectiveness

Gelita-Spon® Absorbable Gelatin Sponge
Summary of Safety and Effectiveness

Submitter Name:	CuraMedical, BV
Submitter Address:	Osdorperweg 590 Amsterdam, NL-1067 SZ, The Netherlands
Contact Person:	Rik Van Beek QA Manager
Phone Number:	011 31 20 667 5330
Fax Number:	011 31 20 667 5331
Date Prepared:	31 May 2005
Device Trade Name:	Gelita-Spon® Absorbable Gelatin Sponge (Gelita-Spon®)
Classification Name, Number & Product Code:	Intranasal Splint (21 CRF 874.4780) LYA; Ear, Nose and Throat Synthetic Polymer Material (21 CRFR 874.3620) KHJ
Predicate Devices:	MeroPack™ Nasal Dressing and Sinus Stent MeroGel™ Nasal Dressing and Sinus Stent
Device Description and Statement of Intended Use	Gelita-Spon® Absorbable Gelatin Sponge is a sterile absorbable gelatin sponge composed of highly purified pH neutral pharmaceutical gelatin of porcine origin with haemostatic effect suitable for the control of bleeding and as a packing material. It is able to absorb blood corresponding to about 50 times its own weight and when implanted in vivo, it is completely absorbed within approximately 3 weeks. Gelita-Spon is indicated for use to control minimal bleeding by tamponade effect, blood absorption and platelet aggregation following ENT surgery and also to prevent adhesions in the nasal cavity.
Summary of Technological Characteristics	A table comparing Gelita-Spon to the predicate devices is attached. This comparison demonstrates the substantial equivalence of Gelita-Spon to the predicate devices.

Feature	Gelita-Spon®	MeroPack™ Nasal Dressing and Sinus Stent	MeroGel™ Nasal Dressing and Sinus Stent
510(k) Number		K041381	K21397
Manufacturer	CuraMedical, B.V.	Medtronic Xomed, Inc.	Medtronic Xomed, Inc.
Classification # & Product Code	21 CFR 874.4780 and 21 CFR 874.3620 LYA/KHJ	21 CFR 874.4780 LYA	21 CFR 874.3620 KHJ
Intended Use	Post-Op, help control minimal bleeding by tamponade effect, blood absorption and platelet aggregation following ENT surgery and also to prevent adhesions in the nasal cavity.	Post-Op, help control minimal bleeding and separate mucosal surfaces/adhesion prevention	Space occupying dressing and/or stent to separate mucosal surfaces, help control minimal bleeding and aid in the natural healing process in the middle and external ear canal
Material/Construction	Porcine-derived gelatin (derived from collagen)	Esterified hyaluronic acid and collagen	Esterified hyaluronic acid
Absorbent Qualities	40 times weight of the device	In excess of 10 times weight of the device	In excess of 10 times weight of the device
Sterility	Gamma radiation	Gamma radiation	Gamma radiation
Resorption Time	Within 21 days	Within 14 days	Within 14 days
Biocompatibility	ISO 10993	ISO 10993	ISO 10993
Method of Action	Hygroscopic, forms gelatinous mass in contact with fluids	Hygroscopic, forms gelatinous mass in contact with fluids	Hygroscopic, forms gelatinous mass in contact with fluids
Method of Removal	Gentle irrigation of residues or natural resorption	Gentle irrigation of residues or natural resorption	Gentle irrigation of residues or natural resorption

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 6 2005

CuraMedical, BV
c/o William Greenrose
President
Qserve America, Inc.
220 River Road
Claremont, NH 03743

Re: K051911
Trade/Device Name: Gelita-Spon® Absorbable Gelatin Sponge (Gelita-Spon)
Regulation Number: 21 CFR 874.3620
Regulation Name: Ear, nose and throat synthetic polymer material
Regulatory Class: Class II
Product Code: KHJ, LYA
Dated: November 3, 2005
Received: November 8, 2005

Dear Mr. Greenrose:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (301) 827-8910. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

David M. Whipple
Acting Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 5.0

Indications for Use Statement

510(k) Number (if known): K051911

Device Name: Gelita-Spon® Absorbable Gelatin Sponge (Gelita-Spon®)

Indications for Use:

Gelita-Spon® Absorbable Gelatin Sponge is indicated for use to control minimal bleeding by tamponade effect, blood absorption and platelet aggregation following ENT surgery and also to prevent adhesions in the nasal cavity.

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

Concurrence of CDRH; Office of Device Evaluation (ODE)

Prescription Use (Per 21 CFR 801.109)	X	OR	Over-The-Counter Use		

(Optional Format 1-2-96)

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

510(k) Number K051911