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
Phone Number: 011 31 20 667 5330
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Date Prepared: 31 May 2005

Device Trade Name: Gelita-Spon® Absorbable Gelatin Sponge (Gelita-Spon®)
Classification Name, Intranasal Splint (21 CRF 874.4780) LYA; Ear, Nose and Throat
Number & Synthetic Polymer Material (21 CRFR 874.3620) KHJ

Product Code: MeroPack™ Nasal Dressing and Sinus Stent
MeroGel™ Nasal Dressing and Sinus Stent

Device Description
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.
<table>
<thead>
<tr>
<th>Feature</th>
<th>Gelita-Spon®</th>
<th>MeroPack™ Nasal Dressing and Sinus Stent</th>
<th>MeroGel™ Nasal Dressing and Sinus Stent</th>
</tr>
</thead>
<tbody>
<tr>
<td>510(k) Number</td>
<td>K041381</td>
<td>K21397</td>
<td></td>
</tr>
<tr>
<td>Manufacturer</td>
<td>CuraMedical, B.V.</td>
<td>Medtronic Xomed, Inc.</td>
<td>Medtronic Xomed, Inc.</td>
</tr>
<tr>
<td>Intended Use</td>
<td>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.</td>
<td>Post-Op, help control minimal bleeding and separate mucosal surfaces/adhesion prevention</td>
<td>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</td>
</tr>
<tr>
<td>Material/Construction</td>
<td>Porcine-derived gelatin (derived from collagen)</td>
<td>Esterified hyaluronic acid and collagen</td>
<td>Esterified hyaluronic acid</td>
</tr>
<tr>
<td>Absorbent Qualities</td>
<td>40 times weight of the device</td>
<td>In excess of 10 times weight of the device</td>
<td>In excess of 10 times weight of the device</td>
</tr>
<tr>
<td>Sterility</td>
<td>Gamma radiation</td>
<td>Gamma radiation</td>
<td>Gamma radiation</td>
</tr>
<tr>
<td>Resorption Time</td>
<td>Within 21 days</td>
<td>Within 14 days</td>
<td>Within 14 days</td>
</tr>
<tr>
<td>Biocompatibility</td>
<td>ISO 10993</td>
<td>ISO 10993</td>
<td>ISO 10993</td>
</tr>
<tr>
<td>Method of Action</td>
<td>Hygroscopic, forms gelatinous mass in contact with fluids</td>
<td>Hygroscopic, forms gelatinous mass in contact with fluids</td>
<td>Hygroscopic, forms gelatinous mass in contact with fluids</td>
</tr>
<tr>
<td>Method of Removal</td>
<td>Gentle irrigation of residues or natural resorption</td>
<td>Gentle irrigation of residues or natural resorption</td>
<td>Gentle irrigation of residues or natural resorption</td>
</tr>
</tbody>
</table>
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 X OR Over-The-Counter Use
(Per 21 CFR 801.109)

(Optional Format 1-2-96)

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

510(k) Number K051911