510(k) Summary

K060878

APR 20 2006

Submitter Name:	CuraMedical, BV
Submitter Address:	Osdorperweg 590 Amsterdam, NL-1067 SZ, The Netherlands
Phone Number:	011 31 20 667 5330
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Contact Person:	Rik Van Beek
Date Prepared:	26 March 2006
Device Trade Name:	Gelita-Spon® Absorbable Gelatin Sponge, USP (Gelita-Spon)
Common Name	Gelatin Sponge
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:	Gelita-Spon® Absorbable Gelatin Sponge
Device Description and Statement of Intended Use	Gelita-Spon® Absorbable Gelatin Sponge USP 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 identical to the predicate device in components, composition, specification, manufacture and packaging. Additional testing to confirm compliance with all test criteria in the USP, specifically including certain biocompatibility tests the methodology of which are slightly different from ISO 10993, was performed following FDA guidance in order to append 'USP' to the product name. Gelita-Spon® Absorbable Gelatin Sponge USP 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.
Conclusion	The information discussed above demonstrates that Gelita-Spon® Absorbable Gelatin Sponge, USP is as safe, as effective, and performs as well as or better than the predicate device, Gelita-Spon® Absorbable Gelatin Sponge.
Declarations	○ This summary includes only information that is also covered in the body of the 510(k). ○ This summary does not contain any puffery or unsubstantiated labeling claims. ○ This summary does not contain any raw data, i.e., contains only summary data. ○ This summary does not contain any trade secret or confidential commercial information. ○ This summary does not contain any patient identification information.

Summary of Technical Characteristics

Feature	Gelita-Spon® Absorbable Gelatin Sponge, USP	Gelita-Spon® Absorbable Gelatin Sponge
510(k) Number		K051911
Manufacturer	CuraMedical, B.V.	CuraMedical, B.V.
Classification # & Product Code	21 CFR 874.4780 and 21 CFR 874.3620 LYA/KHJ	21 CFR 874.4780 and 21 CFR 874.3620 LYA/KHJ
Intended 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	To control minimal bleeding by tamponade effect, blood absorption and platelet aggregation following ENT surgery and also to prevent adhesions in the nasal cavity
Material/Construction	Porcine-derived gelatin (derived from collagen)	Porcine-derived gelatin (derived from collagen)
Absorbent Qualities	40 times weight of the device	40 times weight of the device
Sterility	Gamma radiation	Gamma radiation
Resorption Time	Within 21 days	Within 21 days
Biocompatibility	ISO 10993 and USP	ISO 10993
Method of Action	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

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 13 2006

CuraMedical B.V.
c/o Mr. William F. Greenrose
QServe America, Inc.
220 River Road
Claremont, NH 03743

Re: K060787
Trade/Device Name: CuraMedical's Gelita-Spon® Absorbable Gelatin Sponge, USP
Regulation Number: 21 CFR 874.3620
Regulation Name: ENT Synthetic Polymer Material
Regulatory Class: Class II
Product Code: KHJ; LYA
Dated: March 29, 2006
Received: March 31, 2006

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,

Malvina B. Eydelman, M.D.
Division Director
Division of Ophthalmic and Ear,
Nose and Throat Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Section 2.0

Indications for Use Statement

510(k) Number (if known): _____

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

Indications for Use:

Gelita-Spon® Absorbable Gelatin Sponge, USP 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 K060787

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR 2 0 2006

CuraMedical B.V.
c/o Mr. William F. Greenrose
QServe America, Inc.
220 River Road
Claremont, NH 03743

Re: K060878
Trade/Device Name: Gelita-Spon® Absorbable Gelatin Sponge, USP
Regulation Number: 21 CFR 874.3620
Regulation Name: ENT Synthetic Polymer Material
Regulatory Class: II
Product Code: KHJ, LYA
Dated: March 29, 2006
Received: March 31, 2006

Dear Mr. Greenrose:

This letter corrects our substantially equivalent letter of April 13, 2006.

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 (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.

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Sincerely yours,

Malvina B. Eydelman, M.D.
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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 K060878