510(k) Summary

6.1 Summary Information

6.1.1 Submitter's Name and Address

OCT - 6 2006

Argentum LLC
240 81st Street
Willowbrook, IL 60527

Contact person and telephone number:

Thomas Miller
Telephone: (708) 927-9398
Telefax: (630) 986-4401
E-mail: temiller@aol.com

6.1.2 Device Name

Silverlon™ CA Calcium Alginate Dressing-Antimicrobial Silver

6.1.3 Identification of predicate device substantial equivalence is being claimed

Equivalence is being claimed for prior Silverlon products distributed by Argentum Medical, LLC and for approved Silver Alginate dressings ADRI -K011618; Westaim – K002896 and Advanced Medical Solutions – K041316

6.1.4 Device Description

Silverlon™ CA Advanced Antimicrobial Alginate Dressing, is a sterile, non-woven pad composed of a High M (manuronic acid) alginate and a silver nylon contact layer. It has a light grey appearance. Formatted in various sizes (2" x 2", 4.25" x 4.25", 4" x 8", 8" x 12", and a ¾" x 12" rope) and packaged in Tyvek pouches. The release of silver ions provides an antimicrobial barrier, which protects the dressing from bacterial contamination. The dressing absorbs exudates, maintains a moist wound environment and allows for intact removal.

6.1.5 Statement of the intended use of the device, including general description of the conditions the device will mitigate and the patient population for which the device is intended.

As described in the product label –

Indications

Silverlon™ CA Advanced Antimicrobial Alginate Dressing is an effective barrier to microbial penetration for moderate to heavy exudating partial and full-thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, donor and graft sites, traumatic and surgical wounds and 1st and 2nd degree burns. Silverlon™ CA Advanced Antimicrobial Dressing is indicated for external use only.

6.1.6 Statement of how the technological characteristics of the device compare to those of the predicate device

Silver content is identical to the predicate device. Alginate amount per square inch is identical to the predicate device.

6.2 Assessment of Performance Data

Non-clinical studies showed good balance of tolerability and safety. Three studies were conducted:

- Systemic Injection Test in Mice
- Cytotoxicity – Agar Diffusion
- Primary Dermal Irritation in Rabbits

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT - 6 2006

Argentum Medical, LLC
% Clementi-King, Ltd.
William A. Clementi, Pharm.D., F.C.P.
8 Tower Bridge, Suite 1045
161 Washington Street
Conshohocken, Pennsylvania 19428

Re: K053590
Trade/Device Name: Silverton™ CA Antimicrobial Calcium Alginate Dressing
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 10, 2006
Received: August 14, 2006

Dear Dr. Clementi:

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 (240) 276-0115. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Barbara Melkerson for

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K053590

Device Name: Silverlon™ CA Antimicrobial Calcium Alginate Dressing

Indications for Use:

Silverlon™ CA Advanced Antimicrobial Alginate Dressing is an effective barrier to microbial penetration for moderate to heavy exudating partial and full-thickness wounds, including pressure ulcers, venous ulcers, diabetic ulcers, donor and graft sites, traumatic and surgical wounds and 1st and 2nd degree burns. Silverlon™ CA Advanced Antimicrobial Dressing is indicated for external use only.

Prescription Use __X____ (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 OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Mullis

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K053590