K091133
page 1 of 2

510(k) SUMMARY
Occlusive Wound Dressing
Date of Summary: 04/17/09

MAY 20 2009

A. General Provisions

Submitter's Name:	Aplion Medical, LLC.
Submitter's Address:	2425 South 900 West Salt Lake City, UT 84119
Contact Person:	Curtis Jensen Quality Manager, Ceramatec, Inc.
Classification Name:	Occlusive Wound Dressing 21 CFR 878.4020
Proprietary Name:	Aplion Topical Care System
Common Name:	Occlusive Wound Dressing

B. Name of Predicate Device(s)

- Occlusive Wound Dressing (Product Code – NAD): K020781
  Kinetic Concepts, Inc., Wound Cell Transparent Dressing
- Occlusive Wound Dressing (Product Code – NAD): K060046
  Enzysurge, Ltd., Dermastream

C. Device Description

An occlusive wound dressing is a nonresorbable, sterile or non-sterile device intended to cover a wound, to provide or support a moist wound environment, and to allow the exchange of gasses such as oxygen and water vapor through the device. It consists of a piece of synthetic polymeric material, such as polyurethane, with or without an adhesive backing (21 CFR 878.4020).

The Aplion Topical Care System ("Aplion System") consists of an occlusive wound dressing, a tubeset connection, and a small fluid-delivery component.

D. Indications for Use

The Aplion Topical Care System is an occlusive wound dressing which is intended to provide a moist wound healing environment to facilitate the normal wound healing process. It also permits the introduction of topical wound treatment solutions and suspensions.

E. Safety and Biocompatibility

Safety and Biocompatibility Summary

As a Class I, 510(k) exempt device, FDA review of the Aplion System is not necessary; nonetheless the materials used in the Aplion System were chosen for their biocompatibility, function, and suitability for the intended use of the device. Biocompatibility testing of the entire system was completed according to ISO 10993-1 and 510(k) Memorandum G95-1. Details on the individual materials and the biocompatibility test results are included in this submission.

The Aplion System has been tested to and complies with all applicable Safety and Biocompatibility Standards.

F. Conclusion

The Aplion System, subject of this 510(k), is substantially equivalent to the Wound Cell Transparent Dressing (Kinetic Concepts; K020781) and the Dermastream (Enzysurge; K060046) products previously cleared by FDA.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 20 2009

Aplion Medical, LLC
% Ceramatec, Inc.
Mr. Curtis Jensen
Quality Manager
2425 South 900 West
Salt Lake City, Utah 84119

Re: K091133
Trade/Device Name: Aplion Topical Care System
Regulation Number: 21 CFR 878.4020
Regulation Name: Occlusive wound dressing
Regulatory Class: I
Product Code: NAD
Dated: April 17, 2009
Received: April 20, 2009

Dear Mr. Jensen:

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 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 contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at

(240) 276-0115. 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 contact the CDRH/Office of Surveillance and Biometrics/Division of Postmarket Surveillance at (240) 276-3464. For more information regarding the reporting of adverse events, please go to http://www.fda.gov/cdrh/mdr/.

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,

Mark N. Melkerson
Division of Surgical, Orthopedic
and Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K091133

Device Name: Aplion Topical Care System

Indications for Use: The Aplion Topical Care System is an occlusive wound dressing which is intended to provide a moist wound healing environment to facilitate the normal wound healing process. It also permits the introduction of topical wound treatment solutions and suspensions.

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

David Krause for MXM

(Division Sign-Off)
Division of Surgical, Orthopedic,
and Restorative Devices

510(k) Number K091133