October 27, 2022

Augustine Medical, Inc.
Scott D. Augustine, M.D.
Chief Executive Officer
10393 West 70th Street
Eden Prairie, Minnesota 55344

Re: K020077
Trade/Device Name: Augustine Medical Wound Care System, Model 68XXX
Regulation Number: 21 CFR 878.4020
Regulation Name: Occlusive Wound Dressing
Regulatory Class: Class I
Product Code: MSA

Dear Scott D. Augustine, M.D.:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated January 31, 2002. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under regulation number, 878.4020.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control
and Plastic Reconstructive Surgery Devices
OHT4: Office of Surgical
and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 31 2002

Scott D. Augustine, MD
Chief Executive Officer
Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, Minnesota 55344

Re: K020077
Trade/Device Name: Augustine Medical Wound Care System Model 68XXX
Regulatory Class: Unclassified
Product Code: MSA
Dated: January 7, 2002
Received: January 9, 2002

Dear Dr. Augustine:

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 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained 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/dsma/dsmamain.html

Sincerely yours,

Miriam C. Provost

for Celia M. Witten, Ph.D., M.D.
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 (Special): K020077

Device name: Augustine Medical (Trade Name) Wound Care System

Model 68XXX

Indications for use:

The Augustine Medical Wound Care System is intended for the local management of wounds by maintaining moisture and body temperature in the wound bed. It is indicated for partial- and full-thickness wounds, such as venous, arterial and diabetic ulcers, and Stage II through Stage IV pressure ulcers.

PLEASE DO NOT WRITE BELOW THIS LINE—CONTINUE ON ANOTHER PAGE IF NEEDED.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over the Counter Use _____
(Per 21 CFR 801-109)

Miriam C. Provost
(Division Sign-Off)
Division of General, Restorative and Neurological Devices

510(k) Number K020077

K020077 page 1/2

SMDA Summary— Special 510(k) Modified Device

JAN 31 2002

Submitted by:
Augustine Medical, Inc.
10393 West 70th Street
Eden Prairie, MN 55344
Telephone: 952-947-1200

Contact person:
Scott Augustine, MD

Summary date:
December 31, 2001

Device name/trade name:
Wound Cover, Model 68XXX

Common/usual name:
Augustine Medical Wound Care System

Classification name:
Dressing, Wound & Burn, Occlusive

Equivalent marketed device:
Augustine Medical Wound Cover, Model 68XXX, (K963293)

Device description:
The Augustine Medical wound cover is part of the Wound Care System, which includes a power supply/battery charger, temperature control unit, warming card, and a clean dressing called a *wound cover* that supports the warming card and holds it away from the wound and skin.

The wound cover is a disposable, single-patient-use wound dressing. It is comprised of a thin shell, a window, and a foam frame. The shell has an adhesive border to hold the wound cover in place. It is water-resistant and can be easily cleaned. A clear window in the center of the wound cover allows the caregiver to view and assess the wound, and a pocket on top of the window holds the warming card used during warming therapy. The foam frame absorbs wound fluid (exudate), and keeps the pocket above the wound surface so neither the window nor the warming card contact the wound.

Intended use of the device
The wound cover is an integral part of the Wound Care System, which is intended for the local management of wounds by maintaining moisture and body temperature in the wound bed. The system is indicated for partial- and full-thickness chronic wounds such as venous, arterial, diabetic, and Stage II through Stage IV pressure ulcers.

SMDA Summary— Special 510(k) Modified Device/2

Technological characteristics
The modified device has the same technological characteristics of the cleared device. The wound cover is comprised of materials currently marketed in the wound care industry, which have been proven safe and efficacious over years of patient use. All materials are natural latex-free and nonallergenic.

The adhesive used on all four edges of the wound cover is a medical grade adhesive that has been tested in a repeat insult/sensitization study in humans by the supplier. Potential wound abrasion is avoided by presence of an elevated top surface that is supported by a perimeter of foam. The wound cover maintains its integrity as it absorbs fluid.

Test conclusions
No additional testing was performed because the modified device does not differ in design, technology, materials, or size relative to the cleared device, nor its intended use.