October 27, 2022

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

Re: K963293
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 March 28, 1997. 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

MAR 2 8 1997

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

Re: K963293
Augustine Medical Wound Care System, Model 68XXX
Regulatory Class: Unclassified
Product Code: MSA
Dated: February 14, 1997
Received: February 18, 1997

Dear Dr. Augustine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

1. This device may not be labeled for use on third degree burns.

2. This device may not be labeled as having any accelerating effect on the rate of wound healing or epithelization.

3. This device may not be labeled as a long-term, permanent, or no-change dressing, or as an artificial (synthetic) skin.

4. This device may not be labeled as a treatment or a cure for any type of wound.

The labeling claims listed above would be considered a major modification in the intended use of the device and would require a premarket notification submission (21 CFR 807.81). The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practices, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval) it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations (CFR), Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practices (GMP) for Medical Devices: General GMP regulation (21 CFR Part 820) and that, through periodic GMP inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) number: K963293

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

Model 68XXX

Indications for use:

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

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of General Restorative Devices
510(k) Number K963293

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

510(K) ROUTE SLIP

DXK

510(k) NUMBER K963293 PANEL SU DIVISION DGRD BRANCH PRSB

TRADE NAME AUGUSTINE MEDICAL WOUND CARE SYSTEM MODEL 68XXX

COMMON NAME AUGUSTINE MEDICAL WOUND CARE SYSTEM

PRODUCT CODE MGP DRESSING, WOUND AND BURN, OCCLUSIVE

APPLICANT AUGUSTINE MEDICAL, INC.
SHORT NAME AUGUMEDI
CONTACT SCOTT D AUGUSTINE
DIVISION
ADDRESS 10393 WEST 70TH ST.
EDEN PRAIRIE, MN 55344
PHONE NO. (612) 947-1200 FAX NO. (612) 947-1400

MANUFACTURER	REGISTRATION NO.
AUGUSTINE MEDICAL, INC.	2183725
STERIGENICS INTL., INC.	1420032
STERIGENICS INTL., INC.	1058584
ISOMEDIX OPERATIONS, INC.	1450662

DATE ON SUBMISSION 19-AUG-96 DATE DUE TO 510(K) STAFF 04-NOV-96

DATE RECEIVED IN ODE 21-AUG-96 DATE DECISION DUE 19-NOV-96

DECISION __ DECISION DATE _____

SUPPLEMENTS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
S001	21-NOV-96	22-NOV-96	05-FEB-97	20-FEB-97	31-JAN-97
S002	14-FEB-97	18-FEB-97	04-MAY-97	19-MAY-97	

CORRESPONDENCE	SENT	DUE BACK	
C001	05-NOV-96	05-DEC-96	HOLD LETTER
C002	31-JAN-97	02-MAR-97	HOLD LETTER

OTHER SUBMISSIONS	SUBMITTED	RECEIVED	DUE POS	DUE	OUT
ADD-TO-FILE	02-OCT-96	02-OCT-96	01-DEC-96		

Is this 510(k) identified as a Class III device ____YES ✓ NO

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

Re: K963293
Augustine Medical Wound Care System, Model 68XXX
Regulatory Class: Unclassified
Product Code: MSA
Dated: February 14, 1997
Received: February 18, 1997

Dear Dr. Augustine:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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 (the Act). You may, therefore, market your device subject to the general controls provisions of the Federal Food, Drug, and Cosmetic Act (Act) and the following limitations:

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If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4595. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or 301-443-6597 or at its internet address "http://www.fda.gov/cdrh/dsmamain.html".

Sincerely yours,

for Celia M. Witten, Ph.D., M.D.
Director
Division of General and
Restorative Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

FILE COPY

OFFICE	SURNAME	DATE	OFFICE	SURNAME	DATE
HFZ-410	Krause	3/23/97			
Z-410	S. Rhodes	3/27/97			
Z410	DLL	3/20/97			

bcc: HFZ-401 DMC
HFZ-403 RChissler
HFZ-410 DGRD
D.O.

d/t:

f/t:HFZ-410:DXK:BJT:3/25/97

DEPARTMENT OF HEALTH & HUMAN SERVICES — Public Health Service
Food And Drug Administration

March 21, 1997

Memorandum

From: Reviewer(s) - Name(s) David Krause

Subject: 510(k) Number K963293/S2

To: The Record - It is my recommendation that the subject 510(k) Notification:

- ☐ Refused to accept.
- ☐ Requires additional information (other than refuse to accept).
- ☐ Accepted for review _____.
- ☑ Is substantially equivalent to marketed devices. use K-27 SN letter for wound Dressings
- ☐ NOT substantially equivalent to marketed devices.
- ☐ Other (e.g., exempt by regulation, not a device, duplicate, etc.)

Is this device subject to Postmarket Surveillance?	☐YES	☑NO
Is this device subject to the Tracking Regulation?	☐YES	☑NO
Was clinical data necessary to support the review of this 510(k)?	☑YES	☐NO
Is this a prescription device?	☑YES	☐NO
Was this 510(k) reviewed by a Third Party?	☐YES	☑NO

This 510(k) contains:

Truthful and Accurate Statement ☐Requested ☑Enclosed
(required for originals received 3-14-95 and after)

☑A 510(k) summary OR ☐A 510(k) statement

☐ The required certification and summary for class III devices

☑ The indication for use form (required for originals received 1-1-96 and after)

The submitter requests under 21 CFR 807.95 (doesn't apply for SEs):

☐ No Confidentiality ☐ Confidentiality for 90 days ☐ Continued Confidentiality exceeding 90 days

Predicate Product Code with panel and class:	Additional Product Code(s) with panel (optional):
79 MSA-Dressing, Wound & Burn, Heated Occlusive (Unclassified)	79 MGP Occlusive Wound + Burn Dressing

Review: Elizabeth Rhode — PRSA — 3/27/97
(Branch Chief) (Branch Code) (Date)

Final Review: [signature] — 3/27/97
(Division Director) (Date)

Revised: 11-20-96

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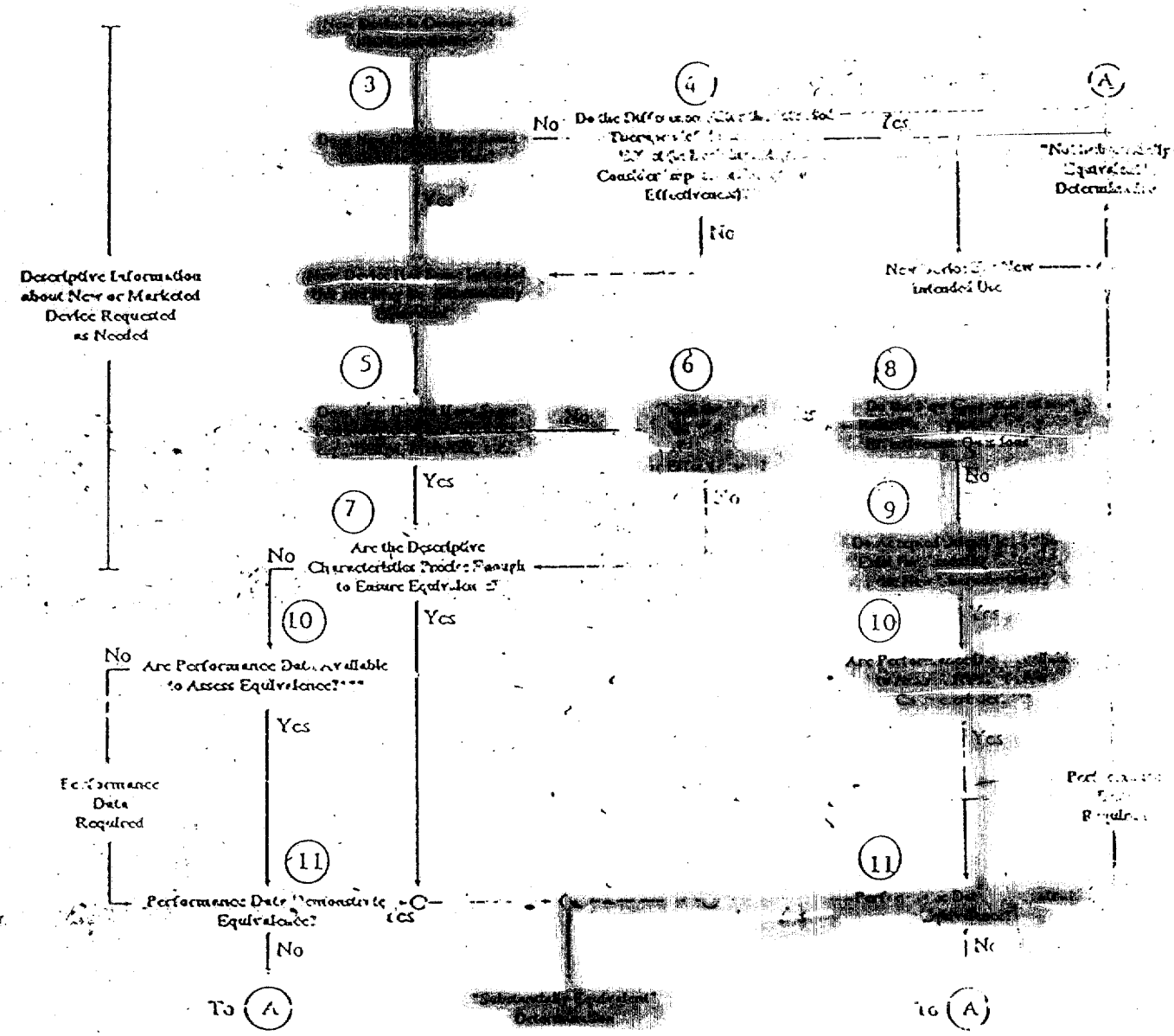
510(k) "SUBSTANTIAL EQUIVALENCE" DECISION-MAKING PROCESS (DETAILED)



* 510(k) submissions compare new devices to marketed devices. FDA requests additional information if the relationship between marketed and "predicate" (pre-Amendments or reclassified post-Amendments) devices is unclear.

** This decision is normally based on descriptive information alone, but limited testing information is sometimes required.

*** Data may be in the 510(k), other 510(k)s, the Center's classification files, or the literature.

REVISED:3/14/95

"SUBSTANTIAL EQUIVALENCE" (SE) DECISION MAKING DOCUMENTATION

K963293

Reviewer: David Krause, Biologist

Division/Branch: DGRD/PRSB

Device Name: Augustine Medical Wound Care System, Model 68XXX

Product To Which Compared [510(K) Number If Known]: ClearSite Wound Dressing (K914207 & K920677), Lyofoam Wound Dressing (K860085) and Seabrook Micro Temp Pump and Pads (K843146).

		YES	NO	
1.	Is Product A Device	X		If **NO** = Stop
2.	Is Device Subject To 510(k)?	X		If **NO** = Stop
3.	Same Indication Statement?	X		If **YES** = Go To 5
4.	Do Differences Alter The Effect Or Raise New Issues of Safety Or Effectiveness?	NA		If **YES** = Stop **NE**
5.	Same Technological Characteristics?		X	If **YES** = Go To 7
6.	Could The New Characteristics Affect Safety Or Effectiveness?	X		If **YES** = Go To 8
7.	Descriptive Characteristics Precise Enough?	NA		If **NO** = Go To 10 If **YES** = Stop **SE**
8.	New Types Of Safety Or Effectiveness Questions?		X	If **YES** = Stop **NE**
9.	Accepted Scientific Methods Exist?	X		If **NO** = Stop **NE**
10.	Performance Data Available?	X		If **NO** = Request Data
11.	Data Demonstrate Equivalence?	X		Final Decision: **SE**

1. **Intended Use:** The subject device is intended to be used for the local management of wounds by maintaining moisture and body temperature in the wound bed and is indicated for partial and full thickness wounds, such as stage I through IV venous, arterial, diabetic, and pressure ulcers. When used in combination with the Wound Cover and Heater Control Unit, the Heater Card is designed to provide heat to the periwound area. The Wound Cover is intended to provide a gas permeable barrier which will absorb wound exudate and maintain a warm and moist periwound environment.

2. **Device Description:** This wound care device (no trade name has been assigned yet) is a wound care treatment system comprised of an adhesive bandage, radiant heater (warming insert), and a heater controller. The system is designed to irradiate a cutaneous ulceration or other wound with infrared energy to raise the periwound temperature. The Augustine Medical Wound Care System is comprised of: a heater control unit (two heater control units are available for the application of temperatures at 38°C and 42°C); a heater card; a sterile/bandage called a Wound Cover which supports the heater card and protects the wound (the wound cover is designed with a clear or opaque window which is elevated from the wound); and a power supply/battery charger. The top of the bandage has a pocket

that accepts the warming insert. The warming insert is connected to the heater controller via a 48.0 inch long detachable electrical cord. The device is considered to be a portable, hand held device.

EXPLANATIONS TO "YES" AND "NO" ANSWERS TO QUESTIONS ON PAGE 1 AS NEEDED

1. **Explain why not a device:** The Augustine Medical Wound Care System is a medical device.

2. **Explain why not subject to 510(k):** This device is subject to 510(k).

3. **How does the new indication differ from the predicate device's indication:** The indications are generally the same.

4. **Explain why there is or is not a new effect or safety or effectiveness issue:** N/A.

5. **Describe the new technological characteristics:** This device has the capability to generate heat at the wound site.

6. **Explain how new characteristics could or could not affect safety or effectiveness:** The heat generated could lead to problems with healing of the wound.

7. **Explain how descriptive characteristics are not precise enough:** N/A.

8. **Explain new types of safety or effectiveness questions raised or why the questions are not new:** The ultimate safety and effectiveness question is will the wound heal.

9. **Explain why existing scientific methods can not be used:** Existing methods can be used.

10. **Explain what performance data is needed:** Clinical work which compares healing of wounds when this device is used and when standard of care treatments are used.

11. **Explain how the performance data demonstrates that the device is or is not substantially equivalent:** Healing rates were not slower when this device was applied.

ATTACH ADDITIONAL SUPPORTING INFORMATION HERE

MEMO TO THE RECORD
510(K) REVIEW
K963293/S2

DATE: March 26, 1997 **OFFICE: HFZ-410**
FROM: Dr. David Krause, Biologist/Reviewer **DIVISION: DGRD/PRSB**

DEVICE NAME: Augustine Medical Wound Care System, Model 68XXX
COMPANY NAME and ADDRESS: Augustine Medical, Inc., 10393 West 70th Street, Eden Prairie, MN 55344

Background: Augustine Medical, Inc. submitted the original 510(k) for this device on August 19, 1996. In a letter dated November 5, 1996, FDA asked for additional information in the form of 7 deficiencies. In a supplement to the original 510(k), dated November 21, 1996, Augustine Medical responded to these deficiencies. All of the questions were adequately addressed except for one. In a letter dated January 31, 1997, FDA responded to K963293/S001. In that response FDA asked Augustine Medical to respond to the following statement: Additional Information is required. This information needs to be in the form of data which evaluate whether or not the device establishes an environment in which healing can take place in the same amount of time as the standard wound care therapies available to patients. Data should be supplied for each type of wound that the sponsor places on his "Indications for Use" form. This supplement (K963293/S002) is Augustine Medical's reply to that statement.

Intended Use: The subject device is intended to be used for the local management of wounds by maintaining moisture and body temperature in the wound bed and is indicated for partial and full thickness wounds, such as stage I through IV venous, arterial, diabetic, and pressure ulcers. When used in combination with the Wound Cover and Heater Control Unit, the Heater Card is designed to provide heat to the periwound area. The Wound Cover is intended to provide a gas permeable barrier which will absorb wound exudate and maintain a warm and moist periwound environment. Both the ClearSite Wound Dressing and the Lyofoam Wound Dressing predicates have almost identical intended uses, except for the heating of the periwound area. The Seabrook device has the intended use of localized heat therapy which is similar to heating the periwound area, although this device is not for open wounds.

Device Description: This wound care device (no trade name has been assigned yet) is a wound care treatment system comprised of an adhesive bandage, radiant heater (warming insert), and a heater controller. The system is designed to irradiate a cutaneous ulceration or other wound with infrared energy to raise the periwound temperature. The Augustine Medical

Wound Care System is comprised of: a heater control unit (two heater control units are available for the application of temperatures at 38°C and 42°C); a heater card; a sterile/bandage called a Wound Cover which supports the heater card and protects the wound (the wound cover is designed with a clear or opaque window which is elevated from the wound); and a power supply/battery charger. The top of the bandage has a pocket that accepts the warming insert. The warming insert is connected to the heater controller via a 48.0 inch long detachable electrical cord. The device is considered to be a portable, hand held device.

Review of Supplement K963293/S002: The deficiency to which Augustine Medical is responding is included in *italics*, Augustine Medical's response will be summarized in **bold print**, while this reviewer's comments will follow in normal type.

> *Additional Information is required. This information needs to be in the form of data which evaluate whether or not the device establishes an environment in which healing can take place in the same amount of time as the standard wound care therapies available to patients. Data should be supplied for each type of wound that the sponsor places on his "Indications for Use" form.*

The sponsor states that, to date, there are seven studies completed or in progress involving different wound types being treated with the Augustine Medical Wound Care System. During all of these studies there have been no reports of any adverse effects or extended healing times when using the Augustine Medical Wound Care System. For Diabetic Ulcers, the median percentage reduction of the wound area per day was 1.86% for standard of care treatment and 2.30% for the Augustine Medical Wound Care Device. For Venous Stasis Ulcers, these values were 3.11% and 3.36%, respectively, for Pressure the values were 1.40% in one study and 2.38% in a second study, while it was 4.85% for the Augustine Device, and finally for Chronic Leg Ulcers the percentage of reduction of wound area was 2.00% for standard of care and 2.65% for the Augustine Wound Care Device.

The sponsor includes a table which shows the data for these studies. The sponsor also includes letters from 4 investigators who are using or have used the Augustine Medical Wound Care System in studies. All of these letters indicate that the Augustine Medical Wound Care System does not impede the healing process and may, indeed, augment healing to some degree. This is an adequate response.

Substantial Equivalence Rationale: When this 510(k) originally came to FDA, on August 19, 1996, there were questions as to whether or not this device would fit the product description of a wound and burn dressing. The fact that the device was heated also raised the possibility that the device would need to be found "Not Substantially Equivalent" because of new types of safety and effectiveness questions. Finally, FDA also needed to know whether

or not the device actually allowed wounds to heal or did it, in fact, inhibit the healing process. All of these issues were raised with the sponsor in a series of telephone and letter requests for additional information.

The Intended Use of the device is equivalent to a wound and burn dressing. As stated on the "Indications for Use" Form: "The Augustine Medical Wound Care System is intended to be used for the local management of wounds by maintaining moisture and body temperature in the wound bed and is indicated for partial and full thickness wounds, such as, stage I through IV venous, arterial, diabetic, and pressure ulcers." Both the ClearSite and Lyofoam Wound Dressings include wound management in the intended uses and specify pressure ulcers (stages I to IV) as indications. The added indications (other types of ulcers) for the Augustine Medical Wound Care System are supported by clinical data which indicate that the wound dressing does, indeed, allow healing to take place at least as well as "standard of care" for these types of ulcers.

The question of heating the periwound area does not raise new questions of safety and effectiveness because the device never raises the temperature of the wound bed above "normal body temperature" which is 37-38°C. Further, the sponsors of the Lyofoam wound dressing included the following claim in their 510(k): "maintains wound temperature to optimize wound healing." The device contains two heater cards, one at 39°C and one at 42°C. The 42°C heater card is not indicated for leg wounds where compromised circulation may be involved, in fact, there is a warning against using the 42°C heater card for these leg wounds. Also, the device is prescription and comes with adequate instructions for use which will assure that the device is only applied by a health care professional.

This device and the additional information which was sent to FDA in response to telephone and letter requests is reviewed in detail in previous memos.

Product Code Update: I received a new product code for this device from Bill Huff on March 18, 1997. The new product code is 79 MSA, Dressing, Wound and Burn, Occlusive, Heated. Please see memos dated March 17 and March 18 for details.

Recommendation: Based on my review of the information included in the original 510(k) submission and the subsequent supplements, I recommend that the subject device, The Augustine Medical Wound Care System, is substantially equivalent to the listed legally marketed predicates (see original review).

Classification: **79 MSA, Dressing, Wound and Burn, Occlusive, Heated (Unclassified)**

David Krause 3/26/97

David Krause, Ph.D. (Date)
Biologist/Reviewer,
Division of General and Restorative Devices
Plastic and Reconstructive Surgery Branch

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Indications for Use

510(k) number (if known):

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

Indications for use:

The Augustine Medical Wound Care System is intended to be used for wound care.

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)

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K963293

510(k) Summary

Augustine Medical Wound Care System

MAR 28 1997

General Information

Classification	Unclassified
Trade Name	Augustine Medical Wound Care System
Submitter	Augustine Medical, Inc. 10993 West 70th Street Eden Prairie, MN 55344 (612) 947-1200
Contact	Scott D. Augustine, MD CEO

Predicate Devices

The Augustine Medical Wound Care System is substantially equivalent in safety and effectiveness in its intended use to these predicate devices:

ClearSite Wound Dressing
K914207 & K920677
Manufactured by NDM Corporation, 3040 E. River Road, Dayton, Ohio 45439-1436, (800) 783-1767

Lyofoam Wound Dressing
K860085
Manufactured by Acme United Corporation, Medical Division, 75 Kings Highway Cutoff, Fairfield, CT 06430-5340, (800) 243-9852

Seabrook MicroTemp Pump and Pads
K843146
Manufactured by Seabrook, Inc. 4043 McMann Road, Cincinnati, OH 45245, (800) 477-7757

Device Description

The wound care system is comprised of a power supply/battery charger, heater control unit, heater card, and a sterile dressing/bandage called a Wound Cover which supports the heater card and holds it away from the wound and skin.

The Wound Cover is a disposable, single-use, sterile, non wound-contact dressing. The Wound Cover may be used either as a stand-alone wound dressing or as part of the Augustine Medical Wound Care System. The Wound Cover incorporates a clear or opaque window. The clear window allows the caregiver to view and assess the tissue. The Wound Cover surrounds and protects the wound, absorbs wound exudate and allows active warming of the periwound area by the application of radiant heat.

The warming components of the system include a thin heater card, a control unit, and a power supply/battery charger. The system operates on standard wall outlet electricity or the self-contained batteries. The heater card is sized appropriately to the Wound Cover and attaches easily over the clear window of the Wound Cover. The heater card does not contact the wound and is intended for single patient use. The control unit incorporates temperature safety limits.

Intended Use

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

Testing

Biocompatibility testing was performed on the materials used in the construction of the sterile dressing. All materials passed biocompatibility testing and are suitable for this application.

Physical testing of the product included: dimensional inspection, functional performance, electrical safety, electromagnetic compatibility, pressure switch activation, overtemperature safety shut-off, and performance under clinical conditions. All testing of the product yielded acceptable results.

Summary of Substantial Equivalence

The Augustine Wound Care System components are constructed of the same or substantially equivalent materials as the predicate products. The sizes and configurations available along with the packaging and sterilization methods are also equivalent.

The clinical indications for use are substantially equivalent to the predicate devices as well.

Therefore, because of the similarity of materials to other wound treatment products, the test results, and the similar indications for use of the predicate devices, Augustine Medical believes these products do not raise any new safety or effectiveness issues.