



Food and Drug Administration
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February 5, 2016

ABL Medical, LLC
% Ms. Calley Herzog
Biologics Consulting Group Incorporated
400 North Washington Street, Suite 100
Alexandria, Virginia 22314

Re: K151185

Trade/Device Name: AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser (Prescription), and AGX Wound Wash Antibacterial Skin and Wound Cleanser (Over-the-Counter)

Regulatory Class: Unclassified

Product Code: FRO

Dated: December 22, 2015

Received: December 28, 2015

Dear Ms. Herzog:

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 note: CDRH does not evaluate information related to contract liability warranties. We remind you; however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to 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); 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 Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>. 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 go to

<http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm> for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Industry and Consumer Education at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address

<http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm>.

Sincerely yours,

David Krause -S

for Binita S. Ashar, M.D., M.B.A., F.A.C.S.
Director
Division of Surgical Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151185

Device Name

AGX Wound Wash Skin and Wound Cleanser and
AGR X Wound Wash Antibacterial Silver Skin and Wound Cleanser

Indications for Use (Describe)

The AGX Wound Wash Skin and Wound Cleanser is indicated for Over the Counter Use -
For normal skin and minor wounds, minor burns, abraded skin, and irritated areas. Aids in removal of excessive skin oils, dirt and debris. Effective cleansing solution.

The AGR X Wound Wash Antibacterial Silver Skin and Wound Cleanser is Indicated for Prescription Use -
To cleanse, moisten and irrigate skin and dermal lesions; Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations. Aids in removal of excessive skin oils, dirt and debris. Effective cleansing solution.

Type of Use (Select one or both, as applicable)

Prescription Use (Part 21 CFR 801 Subpart D)

Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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K151185 - 510(k) Summary

In accordance with 21 CFR 807.87(h) and (21 CFR 807.92) the 510(k) Summary for the AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser and the AGX Wound Wash Skin and Wound Cleanser is provided below.

Device Common Name: Wound Cleanser

Device Proprietary Name: AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser (Prescription)
AGX Wound Wash Skin and Wound Cleanser (Over-the-Counter)

Applicant: ABL Medical, LLC
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Date Prepared: April 30, 2015

Classification Regulation: Unclassified

Panel: General & Plastic Surgery

Product Code: FRO

Predicate Device: K063069, Silvaklenz Antibacterial Silver Skin & Wound Cleanser

Indication for Use:

The AGX Wound Wash Skin and Wound Cleanser is indicated for Over the Counter Use -

For normal skin and minor wounds, minor burns, abraded skin, and irritated areas. Aids in removal of excessive skin oils, dirt and debris. Effective cleansing solution.

The AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser is Indicated for Prescription Use -

To cleanse, moisten and irrigate skin and dermal lesions; Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations. Aids in removal of excessive skin oils, dirt and debris. Effective cleansing solution.

Device Description:

AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser and the AGX Wound Wash Skin and Wound Cleanser are cleansing solutions intended for the external cleansing of skin and wounds. The mechanical action of the fluid moving across the skin or wound surface provides the mechanism of action and aids in the removal of foreign objects such as dirt and debris. The AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser and the AGX Wound Wash Skin and Wound Cleanser are identical devices. The only difference is that the AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser is for prescription use and the AGX Wound Wash Skin and Wound Cleanser is for Over-the-Counter Use.

The solution consists of deionized water containing 10ppm silver. The silver is from American Biotech Labs and is the same silver used in ABL Medical's Wound Dressing hydrogel devices cleared in K140483, K092826 and K082333. The silver acts as a preservative that may help inhibit the growth of microorganisms within the solution while in storage which was established through testing in accordance with USP <51> and was shown to inhibit the growth of microorganisms such as: Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, MRSA, VRE, as well as fungi such as Candida albicans and aspergillus niger.

Performance Testing:Verification Testing

The AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser and the AGX Wound Wash Skin and Wound Cleanser has been tested to verify that it meets its device specifications.

Comparative Testing

The AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser and the AGX Wound Wash Skin and Wound Cleanser specifications were compared to the Silvaklenz Antibacterial Silver Skin & Wound Cleanser cleared in K063069. The specifications were shown to be substantially equivalent.

Biocompatibility Testing

The AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser and the AGX Wound Wash Skin and Wound Cleanser is a patient contacting device, with limited exposure (<24 hours) on breached or compromised surfaces. The AGRX Wound Wash Antibacterial Silver

Skin and Wound Cleanser and the AGX Wound Wash Skin and Wound Cleanser have been evaluated in and passed the following biocompatibility tests:

- Cytotoxicity Biological evaluation of medical devices - ISO 10993-5:2009, Biological evaluation of medical devices - Part 5: Tests for In Vitro cytotoxicity
- Irritation - ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization
- Sensitization - ISO 10993-10: 2010 Biological evaluation of medical devices – Part 10: Tests for irritation and skin sensitization

Antimicrobial Effectiveness

The silver acts as a preservative that may help inhibit the growth of microorganisms within the solution while in storage which was established through testing in accordance with USP <51> and was shown to inhibit the growth of microorganisms such as: Staphylococcus aureus, Pseudomonas aeruginosa, Escherichia coli, Klebsiella pneumoniae, MRSA, VRE, as well as fungi such as Candida albicans and aspergillus niger.

Stability Testing

Stability testing was performed on real time aged samples to establish a shelf life of 3 years. The testing demonstrated that the wound wash maintains its specifications over the three year shelf life.

Substantial Equivalence:

The predicate device for the AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser and the AGX Wound Wash Skin and Wound Cleanser is the Silvaklenz Antibacterial Silver Skin & Wound Cleanser cleared in K063069. A device comparison table is provided in the table below.

	Proposed Device	Predicate Device
510(k) Number	K151185	K063069
Submitter	ABL Medical, LLC	Medical Molecular Therapeutics, LLC
Device Name	AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser AGX Wound Wash and Wound Cleanser	Silvaklenz Antibacterial Silver Skin & Wound Cleanser
Classification Regulation	Unclassified	Unclassified
Product Code	FRO	FRO
Indication	The AGX Wound Wash Skin and Wound Cleanser is indicated for Over the Counter Use -	For Over the Counter Indications -

	Proposed Device	Predicate Device
	<p>For normal skin and minor wounds, minor burns, abraded skin, and irritated areas. Aids in removal of excessive skin oils, dirt and debris. Effective cleansing solution.</p> <p>The AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser is Indicated for Prescription Use -</p> <p>To cleanse, moisten and irrigate skin and dermal lesions; Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor skin irritations.</p> <p>Aids in removal of excessive skin oils, dirt and debris. Effective cleansing solution.</p>	<p>For normal skin and minor wounds, ulcerations and burns, abraded skin, and irritated areas. Aids in removal of excessive skin oils, dirt and debris. Effective cleansing action.</p> <p>For Professional Prescription Indications -</p> <p>To cleanse, moisten and irrigate skin and dermal lesions; Stage I-IV pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts abrasions and minor skin irritations.</p>
Packaging	2oz, 4 oz, 8 oz and 16 oz spray and squeeze bottles	2oz, 4 oz, 8 oz and 16 oz spray and squeeze bottles
Ingredients	Silver solution: deionized water and silver (10 ppm)	Surfactant (soap), cocamidopropyl betaine, silver
Sterile when used?	No	No
Shelf Life	3 years	None claimed
Biocompatibility Testing	<p>Primary Skin Irritation / ISO 10993-10: Tests for Irritation and Sensitization</p> <p>Repeated Patch Dermal Sensitization Test / ISO 10992-10: 2010 Tests for Irritation and Skin Sensitization</p> <p>Agar Overlay / ISO 10993-5: Cytotoxicity</p>	<p>ISO Modified Intracutaneous Study</p> <p>ISO Modified Systemic Toxicity Study</p> <p>ISO Maximization Sensitization</p> <p>Cytotoxicity</p>
Antimicrobial Effectiveness Testing	USP <51>	USP <51>

Conclusion of Substantial Equivalence Evaluation

The subject device is similar in both indications for use and technological characteristics when compared to the predicate device. The subject device and the predicate device have similar labeling, instructions for use and packaging. The only difference between the subject device and the predicate is the ingredients. This difference does not affect the safety of the device as evidenced by the biocompatibility testing and antimicrobial effectiveness testing which is the same testing that was performed on the predicate device. This difference in ingredients does not affect the effectiveness of the subject device based on the fact that the mechanism of action for both the predicate device and the subject device is as a wound wash provided by the mechanical action of the fluid moving across the skin or wound as it is expelled out of the bottle.

Furthermore, the performance testing and the comparative testing confirm that the difference in ingredients does not render the device NSE because this difference does not raise different questions of safety and effectiveness. Therefore the AGRX Wound Wash Antibacterial Silver Skin and Wound Cleanser and the AGX Wound Wash Skin and Wound Cleanser can be found substantially equivalent to the Silvaklenz Antibacterial Silver Skin & Wound Cleanser as cleared in K063069.