DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center – WO66-G609
Silver Spring, MD 20993-0002

October 31, 2014

NAWA Heilmittel GmbH
% Ms. Allyson B. Mullen
Hyman, Phelps & McNamara, P.C.
700 Thirteenth Street, North West
Washington, District of Columbia 20005

Re: K141660
Trade/Device Name: NAWAlution
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 6, 2014
Received: October 6, 2014

Dear Ms. Mullen:

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

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
See PRA Statement below.

510(k) Number *(if known)*
To be determined

Device Name
NAWAlution

Indications for Use *(Describe)*
NAWAlution for prescription use is intended for use under the supervision of healthcare professionals for cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites. It is also intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.

NAWAlution for over-the-counter use is intended for cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor burns.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) *(Signature)*

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 79 hours per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

Department of Health and Human Services
Food and Drug Administration
Office of Chief Information Officer
Paperwork Reduction Act (PRA) Staff
PRAStaff@fda.hhs.gov

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

III. 510(K) SUMMARY

NAWAlution

Submitter Name:	NAWA Heilmittel GmbH
Submitter Address:	Ostendstrasse 100 90482 Nuernberg Germany
Contact Person:	Thomas Riesinger
Phone Number:	011-49-911-5444126
Fax Number:	011-49-911-5444111
Date Prepared:	June 20, 2014
Device Trade Name:	NAWAlution Skin and Wound Cleanser
Device Common Name:	Dressing, Wound, Drug
Product Code:	FRO
Classification:	Unclassified
Predicate Devices:	NeutroPhase Skin and Wound Cleanser, NovaBay Pharmaceuticals, Inc., K113820, Product Code FRO, Unclassified NeutroPhase Skin and Wound Cleanser OTC, NovaBay Pharmaceuticals, Inc., K131542, Product Code FRO, Unclassified Prontosan Wound Irrigation Solution, B. Braun Medical, Inc., K072876, Product Code FRO, Unclassified Prontosan Wound Irrigation Solution, B. Braun Medical, Inc., K110744, Product Code FRO, Unclassified BioDerm Wound Spray, BioDerm Sciences, Inc., K042084, Product Code FRO, Unclassified.
Device Description:	The subject device of this submission is NAWAlution Skin and Wound Cleanser for prescription and OTC use.

	NAWAlution is a clear, colorless liquid intended for the management of wounds. The solution is applied by spraying it directly onto the affected area and/or the dressing. As a result of mechanical action of the solution moving across the wound bed foreign objects, foreign debris and exudate, including, dirt, debris, and microorganisms, are removed from the wound. Moistening and cleansing a wound, such as by using NAWAlution, allows for the natural healing process to take place. NAWAlution for prescription use is supplied in an 8 fluid oz. (237 mL) or 16 fluid oz. (473 mL) spray bottle with a plunger-activated pump applicator. NAWAlution for over-the-counter is supplied in a 50 mL (1.8 fluid oz.) spray bottle with a plunger-activated pump applicator. The solution contains cocamidopropylbetaine, hydrochloric acid, PHMB, zinc/iron, and purified water.
Intended Use:	NAWAlution for prescription use is intended for use under the supervision of healthcare professionals for cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites. It is also intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. NAWAlution for over-the-counter use is intended for cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor burns.
Substantial Equivalence:	The proposed device and the predicate devices have the identical intended use and similar indications for use and technological characteristics, as shown in Table I.1, below. The safety and effectiveness of NAWAlution is supported by biocompatibility testing, functional performance testing, and shelf-life testing conducted with the proposed device.

Table III.1. Proposed and Predicate Device Comparison Matrix

Feature Being Compared	PROPOSED DEVICE NAWAlution Skin and Wound Cleanser	PREDICATE DEVICE NeutroPhase Skin and Wound Cleanser	PREDICATE DEVICE Prontosan Wound Irrigation Solution	PREDICATE DEVICE BioDerm Wound Spray
Indications for Use (Rx)	NAWAlution is intended for use under the supervision of healthcare professionals for cleansing, moistening, debriding, and removal of foreign material including microorganisms and debris from wounds, including acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, venous ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites. It is also intended for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.	K113820: NeutroPhase Skin and Wound Cleanser is intended for use under the supervision of healthcare professionals for cleansing and removal of foreign material including microorganisms and debris from wounds and for moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. It is also intended for moistening and debriding acute and chronic dermal lesions, such as Stage I-IV pressure ulcers, stasis ulcers, leg ulcers, diabetic foot ulcers, post-surgical wounds, first and second degree burns, grafted and donor sites.	K072876: Prontosan Wound Irrigation Solution is intended for prescription use is intended for cleaning wounds and for moistening and lubricating absorbent wound dressings for ulcers, burns, post-surgical wounds and abrasions.	K042084: BioDerm Sciences Wound Spray is intended to cleanse, rinse and externally manage dermal lesions such as lacerations, post-operative (surgical) wounds, partial and full-thickness wounds, burns and ulcers (diabetic, venous stasis, pressure). It may also be used in conjunction with a dressing that absorbs fluids (i.e. gauze, gel, alginate, foam, hydrocolloid).

Feature Being Compared	PROPOSED DEVICE NAWAlution Skin and Wound Cleanser	PREDICATE DEVICE NeutroPhase Skin and Wound Cleanser	PREDICATE DEVICE Prontosan Wound Irrigation Solution	PREDICATE DEVICE BioDerm Wound Spray
Indications for Use (OTC)	NAWAlution Skin and Wound Cleanser for over-the-counter use is intended for cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor burns.	K131542: NeutroPhase Skin and Wound Cleanser OTC is intended for the management of skin abrasions, lacerations, minor irritations, cuts, and intact skin.	K110744: Prontosan Wound Irrigation Solution for over-the-counter use, is intended for cleansing wounds and moistening absorbent wound dressings for the management of minor cuts, abrasions, lacerations and minor burns.	K042084: BioDern Sciences Wound Spray is intended to clean, rinse and externally manage skin wounds such as minor lacerations, minor cuts, minor burns and abrasions.
Biocompatibility	Biocompatible	Biocompatible	Biocompatible	Biocompatible
Appearance	Clear, colorless solution	Colorless	Clear, colorless	Clear, colorless solution
Application method	Spray bottle (50 mL (1.8 fluid oz.) – OTC); Spray bottle (8 fluid oz. (237 mL) or 16 fluid oz. (473 mL) – Rx)	Spray bottle (40 mL)	Tube applicator (40 mL); Squeeze bottle (350 mL)	Spray bottle (100 mL)
Characteristics	Aqueous	Aqueous	Aqueous	Aqueous
Density (at 20°C)	0.9 – 1 g/ml	~ 1.0 g/ml	~ 1.0 g/ml	0.990 – 1.000 g/ml
Materials	Purified water, Cocamidopropylbetaine, Zinc Chloride, PHMB, Hydrochloric acid, Trace Element	Purified water, Sodium Chloride, Sodium Hypochlorite	Purified water, PHMB, Undecylenamidopropyl Betaine	Purified water, Zinc Chloride, Sulfuric Acid, Trace Elements
Buffer	Not buffered	Not buffered	Not buffered	Not buffered

Feature Being Compared	PROPOSED DEVICE NAWAlution Skin and Wound Cleanser	PREDICATE DEVICE NeutroPhase Skin and Wound Cleanser	PREDICATE DEVICE Prontosan Wound Irrigation Solution	PREDICATE DEVICE BioDerm Wound Spray
Sterility	Non-sterile	Non-sterile	Sterile	Non-sterile