DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

September 21, 2017

Anexa Biomedical, Inc.
Ms. Shelly Budloo, J.D.
Executive Management/Quality Manager
40423 Air Time Avenue
Zephyrhills, Florida 33542

Re: K172486
Trade/Device Name: Anexa Wound Flush, Sterile Water and Sterile Normal Saline
Regulatory Class: Unclassified
Product Code: FRO
Dated: August 4, 2017
Received: August 17, 2017

Dear Ms. Budloo:

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: 06/30/2020
See PRA Statement below.

510(k) Number *(if known)*
K172486

Device Name

Anexa Wound Flush, Sterile Water and Sterile Normal Saline

Indications for Use *(Describe)*

For Over-the-Counter Use: For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.

For Prescription Use: For moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as 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 and for device irrigation.

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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510(k) Summary

(As per CFR Title 21 Part 807.92)

A. Administrative

Submitter:

Anexa Biomedical, Inc.
40423 Air Time Ave.
Zephyrhills, FL 33542
813-780-7927

Contact Person:

Shelly Budloo, J.D. - Executive Management/QA Manager

Date of Preparation:

August 4, 2017

B. Device

Device Name:

Sterile Water and Sterile Normal Saline

Proprietary Name:

Anexa Wound Flush, Sterile Water, and Sterile Normal Saline

Common/Usual Name:

Sterile Water and Sterile Normal Saline

Classification:

Unclassified, pre-amendment device

Classification Name:

Dressing, Wound, Drug

Product Code:

FRO

C. Predicates' Devices

Predicates' Devices Names:

Sterile Water and Sterile Normal Saline;
Strukmyer Medical, LLC- K161311

Wound Flush, Sterile Water & Sterile Normal Saline;
Nurse Assist, Inc.- K083042

D. Device Description and Intended Use

Device Description:

The Sterile Water and Sterile Normal Saline devices are wound and device cleaning solutions that are intended for moistening and debriding of dermal wounds and for device irrigation. The solution is either sterile water or sterile normal saline for irrigation and meets the requirements of USP<40>. The devices are offered in 100mL, 250mL, and 500mL bottles, and 120mL cups.

Statement of Device Intended Use:

For Over-the-Counter Use:

For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin.

For Prescription Use:

For moistening absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as 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, and for device irrigation.

E. Device Comparison to Predicates and Discussion of Tests Submitted

Comparison to Predicates' Devices:

Sterile Water and Sterile Normal Saline have the same technological characteristics and provide the same mechanism of action as the predicates' devices, i.e., the mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirt and debris. They are labeled for the same intended uses and are supplied sterile in containers of identical composition.

Discussion of Tests Submitted:

Biocompatibility testing of Sterile Water and Sterile Normal Saline has been conducted.

The devices were found to be non-cytotoxic, non-irritating and non-sensitizing in ISO 10993 standard tests; results which are similar to those reported for the predicates' devices.

F. Conclusion

Based on a comparison of composition, technological characteristics, intended use, and biocompatibility test results, we conclude that Sterile Water and Sterile Normal Saline perform at least as well as the predicates' devices. Sterile Water and Sterile Normal Saline are therefore considered to be substantially equivalent to the above- mentioned predicates' devices.

Predicates' Devices Comparison Chart

	Subject	Predicate	Predicate	Predicate	Similarities & Differences
Submitter/holder	Anexa Biomedical, Inc.	Strukmyer Medical, LLC	Nurse Assist, Inc.	Anexa Biomedical, Inc.	
K Number	K172486	K161311	K083042	K161658	
Device/Trade/ Brand Name	Anexa Wound Flush, Sterile Water and Sterile Normal Saline	Sterile Water and Sterile Normal Saline	Wound Flush, Sterile Water and Sterile Normal Saline	Wound Flush, Sterile Water and Normal Saline	Same
Classification	Unclassified, pre-amendment	Unclassified, pre-amendment	Unclassified, pre-amendment	Unclassified, pre-amendment	Same
Product Code	FRO	FRO	FRO	FRO	Same
Indications for Use	For Over-the-Counter Use: For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. For Prescription Use: For moistening	For Over-the-Counter Use: For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. For Prescription Use: For moistening	For Over-the-Counter Use: For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skin. For Prescription Use: For moistening	Not for Over-the-Counter Use For Prescription Use:	Same K172486 K161311 K083042 Different K161658

	absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as 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 and for device irrigation.	absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as 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 and for device irrigation.	absorbent wound dressings and for moistening, debriding and cleaning acute and chronic dermal lesions, such as 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 and for device irrigation.	For moistening of absorbent wound dressings and irrigation to remove loose debris and dirt from the wound.	Same K172486 K161311 K083042 Different K161658
Principle of Operation	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirt and debris.	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirt and debris.	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirt and debris.	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirt and debris.	Same
Chemical Composition	0.9% Sterile Saline or Sterile Water; no antimicrobial or other substance added	0.9% Sterile Saline or Sterile Water; no antimicrobial or other substance added	0.9% Sterile Saline or Sterile Water; no antimicrobial or other substance added	0.9% Sterile Saline or Sterile Water; no antimicrobial or other substance added	Same
Models	8100 - 100mL USP Sterile Water 9100 – 100mL USP Sterile Saline 8250 - 250mL USP Sterile Water 9250 – 250mL USP Sterile Saline 8500 - 500mL USP Sterile Water 9500 – 500mL USP Sterile Saline 8120 - 120mL USP Sterile Water 9120 – 120mL USP Sterile Saline	Model Numbers Unknown but sizes are the same: 100mL USP Sterile Water 100mL USP Sterile Saline 120mL USP Sterile Water 120mL USP Sterile Saline 250mL USP Sterile Water 250mL USP Sterile Saline 500mL USP Sterile Water 500mL USP Sterile Saline	6250 - 100mL USP Sterile Water 6240– 100mL USP Sterile Saline 6260 - 250mL USP Sterile Water 6270 – 250mL USP Sterile Saline 6290 - 500mL USP Sterile Water 6280 – 500mL USP Sterile Saline 6210 - 120mL USP Sterile Water 6220 – 120mL USP Sterile Saline	8100 - 100mL USP Sterile Water 9100 – 100mL USP Sterile Saline 8250 - 250mL USP Sterile Water 9250 – 250mL USP Sterile Saline 8500 - 500mL USP Sterile Water 9500 – 500mL USP Sterile Saline 8120 - 120mL USP Sterile Water 9120 – 120mL USP Sterile Saline	Same

The Indications for Use of the Anexa Wound Flush, Sterile Water & Sterile Normal Saline are identical to the predicates' devices.

The technological characteristics (Design and Materials) of the Anexa Wound Flush, Sterile Water & Sterile Normal Saline are identical to the predicates' devices.

Non-Clinical Testing

ASTM F1980-07 (Reapproved 2011)
AATNU / ANSI/ ISO 11607-1:2006/(R)2010
AAMI / ANSI / ISO 11607-2:2006/(R)2010
AAMI / ANSI / ISO 11607-2:2006/(R)2010
AAMI / ANSI / ISO 11137-1:2006/(R)2010
AAMI / ANSI / ISO 11137-2:2013
AAMI / ANSI / ISO 11737-1:2006 (R)2011
AAMI / ANSI / ISO 11737-2:2009/(R)2014
AAMI / ANSI / ISO 10993-1:2009/(R) 2013
AAMI / ANSI / ISO 10993-5:2009/(R) 2014
ISO 10993-10 Third Edition 2010-08-01
AAMI / ANSI / ISO 10993-11:2006/(R)2010
AAMI TIR 22:2007
AAMI TIR 33:2005
AAMI/ANSI/ISO TIR 13004:2013

Substantial Equivalence

To establish substantial equivalence to the predicates' devices, Anexa evaluated the indications for use, material, technology, and specifications of the device. Through safety and performance testing, Anexa has concluded that the device does not introduce any significant questions of safety and efficacy and is substantially equivalent to the predicates' devices.