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

September 14, 2016

Anexa Biomedical, Inc.
% Ms. Yolanda Smith
Smith Associates
1468 Harwell Avenue
Crofton, MD 21114

Re: K161658
Trade/Device Name: Anexa Wound Flush, Sterile Water & Sterile Normal Saline
Regulatory Class: Unclassified
Product Code: FRO
Dated: June 14, 2016
Received: June 16, 2016

Dear Ms. Smith:

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 on last page.

510(k) Number *(if known)*
K161658

Device Name
Wound Flush, Sterile Water & Normal Saline

Indications for Use *(Describe)*

For moistening of absorbent wound dressings and irrigation to remove loose debris and dirt from the wound.

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)*

510(k) Summary
K161658
(As Per 21 CFR 807.92)

SPONSOR

Company Name:	Anexa Biomedical, Inc.
Company Address:	40423 Air Time Ave Zephyrhills, Florida 33542
Telephone: Fax:	813-780-7927 813-780-7930
Contact Person:	Lenny Budloo

Summary Prepared	September 12, 2016
Trade Name:	Anexa Sterile Water, Normal Saline
Common/Usual Name:	Sterile Water, Normal Saline, Wound Flush Solution
Classification Name:	Dressing, Wound, Drug
Product Code:	FRO
Device Class:	Unclassified
Regulation Number:	

Predicate Device

Company	***Product***	***510(k)#***
Nurse Assist, Inc.	Wound Flush, Sterile Water & Sterile Normal Saline	K083042

Device Description

The Wound Flush, Sterile Water & Sterile Normal Saline device can be used 1) for moistening a dry sterile dressing for wound cleansing and 2) irrigation to remove loose debris and dirt from the wound. The mechanical action of fluid moving across the wound provides the mechanism of action and aids in the removal of loose foreign material such as dirt and debris. The product has a shelf life of 2-years.

The solution is available as sterile water or sterile saline for irrigation and is gamma sterilized. The subject device is offered in various bottle sizes of 100ml, 250ml, and 500ml and cup sizes of 120ml.

Indications for Use

For moistening of absorbent wound dressings and irrigation to remove loose debris and dirt from the wound.

Comparison of Technological Characteristics

	Subject	Predicate Nurse Assist, Inc.	Similarities and Difference
K Number		K083042	
Brand Name	Anexa Wound Flush, Sterile Water & Sterile Normal Saline	Nurse Assist Wound Flush, Sterile Water & Sterile Normal Saline	
Classification Product Code	FRO	FRO	Same
Classification	Pre-amendment	Pre-amendment	Same
Indications for Use	For moistening of absorbent wound dressings and irrigation to remove loose debris and dirt from the wound.	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.	Similar
Principle of Operation	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as loose 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	Similar
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	Same

Models	8100 100 mL Sterile Water 9100 100 mL Sterile Saline 8250 250 mL Sterile Water 9250 250 mL Sterile Saline 8500 500 mL Sterile Water 9500 500 mL Sterile Saline 8120 120 mL Sterile Water 9120 120 mL Sterile Saline	6210 120 mL Sterile Water 6220 120 mL Normal Saline 6240 100 mL Normal Saline 6250 100 mL Sterile Water 6260 250 mL Sterile Water 6270 250 mL Normal Saline 6280 500 mL Normal Saline 6290 500 mL Sterile Water	Same

Discussion of Technological Differences

The subject device and the predicate have similar indications for use and intended use. Both offer bottles with induction sealed pull tab with screw cap closure and high impact polystyrene cups with heat sealed foil lid. The mechanical action is the same for both the subject device and the predicate, as it relates to Sterile Water and Normal Saline bottles and cups. The materials and methods used in the manufacturing and sterilization (gamma) are the same for both devices.

Non Clinical Testing

ASTM F1980-07 (Reapproved 2011)
AAMI / ANSI / ISO 11607-1:2006/(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

Anexa conducted and passed the following biocompatibility tests; cytotoxicity, dermal sensitization, intracutaneous test (direct injection), acute systemic toxicity and bacterial endotoxin test.

Substantial Equivalence Conclusion

The Anexa products passed all the referenced biocompatibility tests, uses the same materials and container designs, same method of sterilization, same principle of operation, and the same intended use(s). Through safety and performance testing, Anexa Biomedical has concluded that the device does not introduce any significant new questions of safety and efficacy and is substantially equivalent to the predicate device.