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

June 23, 2017

L S Scientific, Inc. D.B.A. KSE Scientific
Mr. Jordan Reynolds
Quality Manager
2714 South Miami Blvd.
Durham, NC 27703

Re: K170270
Trade/Device Name: Aqua Care & Accu-Rinse, Sterile Water & Sterile Normal Saline
Regulatory Class: Unclassified
Product Code: FRO
Dated: January 20, 2017
Received: June 20, 2017

Dear Mr. Reynolds:

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)*
K170270

Device Name
Aqua Care & Accu-Rinse, Sterile Water & Sterile Normal Saline

Indications for Use *(Describe)*
OTC: For moistening absorbent wound dressings and cleaning minor cuts, minor burns, superficial abrasions and minor irritations of the skins. Not for injection.

Rx: 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. Not for injection.

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.

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.

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5 – 510(k) Summary

(In accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

1. **Submitter's name and address:**

   LS Scientific Inc, D.B.A. KSE Scientific
   2714 S Miami Blvd
   Durham, NC 27703

2. **Submitter's telephone number and fax number:**

   Tel: (919) 597-3500
   Fax: (919) 597-3510

3. **Contact person:**

   Jordan Reynolds – Quality Manager

4. **Date this 510(k) summary prepared:**

   January 20, 2017

5. **Trade/proprietary name of the device:**

   Aqua Care & Accu-Rinse Sterile Water & Sterile Normal Saline

6. **Device classification**

   Unclassified, pre-amendment device
   Product Code FRO

7. **Legally marketed predicate devices to which substantial equivalence is claimed:**
   - Wound Flush, Sterile Water & Normal Saline; Nurse Assist, Incorporated – K083042
   - Welcon Sterile Water for Device Irrigation, Welcon Sterile 0.9% Normal Saline; Nurse Assist, Incorporated – K003402

8. **Description of the device that is the subject for this premarket notification:**
   Aqua Care & Accu-Rinse, Sterile Water & Sterile Normal Saline device is a wound and device cleansing solution that is intended for moistening and debriding of dermal wounds and for device irrigation. The solution is either sterile water or sterile saline for irrigation and meets all of the associated requirements defined in the USP. The subject device is offered in various bottle and cup sizes.

9. **Intended use and indication 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. Not For Injection.
   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. Not For Injection.

10. **Technological characteristics:**
    The mechanical action of fluid moving across the wound or device provides for the mechanism of action and aids in the removal of foreign objects such as dirt and debris.

11. **Summary of testing:**
    Testing was performed on the Sterile Water for Irrigation to show conformance to the USP monograph for Water for Irrigation. These tests included endotoxin, total organic carbon, pH, chloride, sulfate, ammonia, calcium, carbon dioxide, and oxidizable substances. In addition to the aforementioned testing, as the product is being sold as "sterile", the product was tested accordingly. To achieve validation of sterility parameters, a VDmax study was conducted to determine irradiation parameters. The results of the VDmax study can be found on pages 14-6 through 14-27. A summary of all lots tested can be found in summary tables on page 14-3 and 14-4. As the sodium chloride used in the Sterile Normal Saline conforms to the USP monograph for *Sodium Chloride*, chemical analysis was not required to show conformance to the monograph.

12. Conclusion:

At this time, it is the belief of KSE Scientific that our candidate derives show substantial equivalence to the predicate devices. Due to the candidate device showing conformance to the prescribed monographs for each material, establishing the same irradiation parameters, indications of use, packaging materials, and biocompatibility, we have shown the equivalence to the predicate devices. A summary table can be found on the following page showing these substantiated claims.

This concludes the 510(k) Summary.

	Candidate Device	Predicate Devices	
	Aqua Care & Accu-Rinse, Sterile Water & Sterile Normal Saline	**Welcon Sterile Water and Sterile 0.9% Normal Saline**	**Nurse Assist Wound Flush, Sterile Water & Normal Saline**
510(k) number		K003402	K083042
510(k) owner/submitter	KSE Scientific	Nurse Assist, Inc	Nurse Assist, Inc
Classification Product Code	Pre-amendment, unclassified, FRO	JOL	Pre-amendment, unclassified, FRO
Intended use: Device Irrigation or Wound Irrigation	X	X	X
	X		X
Over-the-Counter or Prescription	X		X
	X	X	X
Packaging Materials Cups Bottles	HDPE w/Foil Seal HDPE Bottle w/ PP cap	HDPE w/Foil Seal HDPE Bottle w/ PP cap	HDPE w/Foil Seal HDPE Bottle w/ PP cap
Biocompatiability: Conformance Shown	Yes	Yes	Yes
Sterilization Method	Terminal (Gamma)	Terminal (Gamma)	Terminal (Gamma)
Sterile?	Yes	Yes	Yes
Shelf Life	2 years	2 years	2 years
Chemical Composition	Sterile Water for Irrigation or 0.9% Sterile Saline; no antimicrobial or other substance added	Sterile Water for Irrigation or 0.9% Sterile Saline; no antimicrobial or other substance added	Sterile Water for Irrigation or 0.9% Sterile Saline; no antimicrobial or other substance added
Mechanism of Action	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirts and debris	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirts and debris	Mechanical action of fluid moving across the wound or device aids in the removal of foreign objects such as dirts and debris