



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

August 29, 2016

Strukmyer Medical LLC  
% Mr. Richard Hamer  
Richard Hamer Associates LLC  
705 Spring Lakes Blvd.  
Bradenton, Florida 34210

Re: K161311

Trade/Device Name: USP Sterile Water, 120 MI Cup, USP Sterile Normal Saline (0.9% Sodium Chloride), 120 MI Cup, USP Sterile Water, 100 MI, 250 MI And 500 MI Bottles, USP Sterile Normal Saline (0.9% Sodium Chloride), 100 MI, 250 MI And 500 MI Bottles

Regulatory Class: Unclassified

Product Code: FRO

Dated: August 4, 2016

Received: August 9, 2016

Dear Mr. Hamer:

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" (21 CFR 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)

K161311

Device Name

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.

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

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## **510(k) SUMMARY**

### **I. ADMINISTRATIVE**

**Submitter:**

Strukmyer Medical  
1801 Big Town, Suite 100  
Mesquite, TX 75149  
(214) 275-9595

**Contact Person:** Robert (Bob) Delk

**Date of Preparation:** August 5, 2016

### **II. DEVICE NAME**

**Proprietary Name:** Sterile Water and Sterile Normal Saline

**Classification Name:** Unclassified, pre-amendment device; Product Code FRO

### **III. PREDICATE DEVICE**

Sterile Water and Sterile Normal Saline ; K083042, Nurse Assist, Inc.

### **IV. 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 <38>. The devices are offered in 100 mL, 250 mL and 500 mL bottles and 120 mL cups

### **V. 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.

## **VI. COMPARISON TO PREDICATE DEVICE**

Sterile Water and Sterile Normal Saline have the same technological characteristics and provide the same mechanism of action as the predicate 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. 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 predicate devices.

## **VII. 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 predicate devices. Sterile Water and Sterile Normal Saline are therefore considered to be substantially equivalent to the above-mentioned predicate devices.