K083042 1/2

DEC 18 2008

510(k) Section 5
Wound Flush, Sterile Water & Sterile Normal Saline

5 – 510(k) Summary
(In accordance with 21 CFR 807.87(h) and 21 CFR 807.92)

1. **Submitter's name and address:**
   Nurse Assist Incorporated
   3400 Northern Cross Boulevard
   Fort Worth, Texas 76137

2. **Submitter's telephone number and fax number:**
   Tel: (817) 231-1300
   Fax: (817) 231-1500

3. **Contact person:**
   Bill Kanewske - Vice President of Operations

4. **Date this 510(k) summary prepared:**
   October 7, 2008

5. **Trade/proprietary name of the device:**
   Wound Flush, 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:**
   - Welcon Sterile Water and Sterile 0.9% Normal Saline – K973784 and K003402
   - Dermacyn Wound Care; Oculus Innovative Sciences, Incorporated – K060113
   - Revera Wound Care; Revalesio Corporation – K070463
   - BioDerm Wound Spray; BioDerm Sciences, Incorporated – K042084
   - Blairex Wound Wash Saline, Blairex Laboratories, Incorporated – unknown

8. **Description of the device that is the subject of this premarket notification:**
   The Wound Flush, 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 <31>. The subject device is offered in various bottle and cup sizes with and without a spray applicator

510(k) Section 5
Wound Flush, Sterile Water & Sterile Normal Saline

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.
- *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.

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.

This concludes the 510(k) Summary.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

DEC 18 2008

Nurse Assist, Inc.
% Shotwell and Carr, Inc.
Ms. Denice Gallagher
Regulatory Consultant
1415 Halsey Way, Suite 304
Carrollton, Texas 75007-4455

Re: K083042
Trade/Device Name: Wound Flash, Sterile Water & Normal Saline
Regulatory Class: Unclassified
Product Code: FRO
Dated: October 7, 2008
Received: October 14, 2008

Dear Ms. Gallagher:

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.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such 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); 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.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

K083042 1/1

510(k) Section 4
Wound Flush, Sterile Water & Sterile Normal Saline

4 – Indications for Use

510(k) Number (if known): _____
Unknown – not yet assigned by FDA

Device Name: Wound Flush, Sterile Water & Normal Saline

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 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.

Prescription Use (Part 21 CFR 801 Subpart D)	___X___	AND/OR	Over-The-Counter Use (21 CFR 801 Subpart C)	___X___

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MK

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K083042

(Posted November 13, 2003)

Nurse Assist, Inc.