



Food and Drug Administration  
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August 21, 2015

Synedgen Incorporated  
Shenda Baker, Ph.D.  
President and Chief Operating Officer  
1420 North Claremont Boulevard, Suite 105D  
Claremont, California 91711

Re: K143444  
Trade/Device Name: SynePure Wound Cleanser  
Regulatory Class: Unclassified  
Product Code: FRO  
Dated: July 23, 2015  
Received: July 24, 2015

Dear Dr. Baker:

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

## Indications for Use

510(k) Number (if known)

K143444

Device Name

SynePure Wound Cleanser

Indications for Use (Describe)

SynePure™ Wound Cleanser is intended for the cleansing and rinsing of dermal wounds such as pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor irritations of the skin.

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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## 510(k) Summary

### Submitter

Synedgen, Inc.  
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Phone: 909-447-6858  
Fax: 909-447-6801  
Contact Person: Shenda Baker, Ph.D. Date  
Prepared: August 20, 2015

### Device

Name of Device: SynePure WoundCleanser  
Common or Usual Name: SynePure™ Classification:  
Unclassified  
Product Code: FRO

### Predicate Device

ALLCLENZ Wound Cleanser K965120

### Reference Devices:

The PosiSep and PosiSep X Hemostat Dressings (K120958)  
AQUANOVA Ag Super-Absorbent Dressing (K100693)

### Device Description

SynePure is a biocompatible, cleansing solution that is intended for rinsing and cleansing dermal wounds through irrigation. The solution is preserved and provided in flexible low density polyethylene (LDPE) bottles with a nozzle spray top to allow for easy delivery of a stream of liquid to remove dirt, debris and contamination from a wound. A screw cap is used to secure the device when not in use. The cap/bottle assembly is sealed with a strip to indicate tampering.

The wound cleanser is supplied as 125mL single-use or 250mL multiple-use bottle. The mechanical action of fluid moving across the wound provides for the mechanism of action to aid in the removal of foreign objects, such as dirt and debris, from the wound.

### Indications for Use

SynePure™ Wound Cleanser is intended for the cleansing and rinsing of dermal wounds such as pressure ulcers, stasis ulcers, diabetic ulcers, foot ulcers, post-surgical wounds, first and second degree burns, cuts, abrasions and minor irritations of the skin.

### Comparison with Predicate

The candidate device, SynePure, has the same intended use and the substantially equivalent technological characteristics as the following predicate device: ALLCLENZ Wound Cleanser. Both the predicate and the proposed device are aqueous based solutions that use polymers to assist in the removal of debris through irrigation. The proposed device and predicate use sorbitol to balance the solution and to provide a denser solution. The proposed device and predicate are preserved to control microbial content. The proposed device and predicate are delivered with a pH that is not significantly acidic or basic. Like the predicate device, SynePure utilizes the mechanical action of fluid moving

across the wound to aid in the removal of foreign objects such as dirt and debris. Based on the comparison of technological characteristics, indications for use, biocompatibility and mechanism of action, SynePure Wound Cleanser is substantially equivalent to the Predicate Device.

#### Performance Data

Testing was done to assure the fluid spray from the bottle exceeds a minimum duration of delivery. Testing was also done to assure that greater than 90% of the solution is delivered from the bottle.

#### Biocompatibility Testing

Biocompatibility testing was completed according to the ISO 10993 series.

Cytotoxicity of the SynePure device was evaluated and the data indicate that the device is not cytotoxicity.

The ability of SynePure solution to cause delayed-type hypersensitivity was evaluated and the results of the study show no sensitization. These results indicate that the device is not sensitizing.

Acute systemic toxicity evaluation of the SynePure device showed no abnormalities in all animals at all observation times, indicating that the device has no acute systemic toxicity.