

## 510(k) Summary

**Sponsor:** Alcavis HDC LLC  
8322 Helgerman Court  
Gaithersburg, MD 20877

**Contact Person:** Gary J. Mishkin  
Chief Operations Officer  
Tele: (301) 330-7597  
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**Date Prepared:** April 15, 2011

**Device Name:** Proprietary Name: ExSept Skin and Wound Cleanser  
Common Name: Wound Cleanser  
Classification Name: Dressing, Wound, Drug

**Predicate Devices:** ExSept WC Wound Cleaner, K061467  
SilvaKlenz Skin and Wound Cleanser, K063069  
Dermacyn Wound Cleanser, K042729  
Anasept Animicrobial Skin and Wound Cleanser, K073547  
Dakin's Wound Cleanser, K090791

**Device Description:** ExSept Skin and Wound Cleanser is a clear to slight yellow, slight chlorine odor, solution which is intended for the mechanical cleansing of debris and foreign material from

exudating/dirty epidermal and dermal wounds. It is supplied in a 200 ml pump-spray and 100 ml, 250 ml and 500 ml pour bottles. ExSept Skin and Wound Cleanser contains a preservative permitting a 30 month shelf life.

**Intended Use:**

**OTC:** ExSept Skin and Wound Cleanser with is intended for cleansing and removal of dirt, debris and foreign material from minor skin abrasions, minor lacerations, minor skin and nail irritations, minor cuts, and intact skin.

**Professional Use:** Under supervision of healthcare professionals, ExSept Skin and Wound Cleanser is intended for use for mechanical cleansing, debridement and removal of foreign material and debris from exudating and/or dirty wounds, such as stage I-IV pressure ulcers, diabetic foot ulcers, ingrown toe nails, post surgical wounds, first and second degree burns, grafted and donor sites, and exit sites.

**Substantial Equivalence:** ExSept Skin and Wound Cleanser is substantially equivalent in the cleansing functions and intended uses to the predicate devices ExSept WC, SilvaKlenz, Dermacyn, Anasept, and Dakin's. All predicate devices use a flushing action to remove foreign material and other debris from the wounds and surrounding skin.

**Testing:** Numerous in-vitro and in-vivo studies have been performed to demonstrate the efficacy, safety and biocompatibility of the ExSept Skin and Wound Cleanser for the indications for use. Stability studies show a shelf life of 30 months, when stored at room temperature.

**Conclusion:** Based upon the information in the 510(k) submission,

ExSept Skin and Wound Cleanser will perform as intended as a wound cleanser. ExSept Skin and Wound Cleanser is substantially equivalent in its actions and functions as the marketed devices ExSept WC, SilvaKlenz, Dermacyn, Anasept, and Dakin's.



Food and Drug Administration  
10903 New Hampshire Avenue  
Document Control Room -WO66-G609  
Silver Spring, MD 20993-0002

Alcavis HDC, LLC  
% Mr. Gary J. Mishkin  
Chief Operations Officer  
8322 Helgerman Court  
Gaithersburg, Maryland 20877

DEC 14 2011

Re: K111313

Trade/Device Name: Alcavis ExSept Skin and Wound Cleanser  
Regulation Number: 21 CFR 880.5475  
Regulation Name: Jet lavage  
Regulatory Class: II  
Product Code: FQH  
Dated: November 3, 2011  
Received: November 8, 2011

Dear Mr. Mishkin:

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 go to <http://www.fda.gov/AboutFDA/CentersOffices/CDRH/CDRHOffices/ucm115809.htm> for the Center for Devices and Radiological Health's (CDRH's) Office of Compliance. 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 Small Manufacturers, International and Consumer Assistance 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,



*for* Mark N. Melkerson  
Director  
Division of Surgical, Orthopedic,  
and Restorative Devices  
Office of Device Evaluation  
Center for Devices and  
Radiological Health

Enclosure

## Indications for Use

510(k) Number (if known): K111313

Device Name: Alcavis ExSept Skin and Wound Cleanser

### Indications For Use:

**OTC:** ExSept Skin and Wound Cleanser is intended for cleansing and removal of dirt, debris and foreign material from minor skin abrasions, minor lacerations, minor skin and nail irritations, minor cuts, and intact skin.

**Professional Use:** Under supervision of healthcare professionals, ExSept Skin and Wound Cleanser is intended for use for mechanical cleansing, debridement and removal of foreign material and debris from exudating and/or dirty wounds, such as stage I-IV pressure ulcers, diabetic foot ulcers, ingrown toe nails, post surgical wounds, first and second degree burns, grafted and donor sites, and exit sites.

Prescription Use  AND/OR Over-The-Counter Use

(21 CFR 801 Subpart D)

(21 CFR 801 Subpart C)

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

David K...  
(Division Sign-Off)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Division of Surgical, Orthopedic,  
and Restorative Devices

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