

JAN 29 1998

510(k) Summary

Submitted by-Zerowet, Inc.
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Contact person-Keith Stamler, MD
Date-November 10, 1997
Trade name-Zerowet Splashield
Common name-Same
Classification name-Irrigation syringe-Accessory
Predicate legally marketed device-Zerowet Splashield (sterile)

The device of the current submission is an unsterilized styrene bell-shaped unit, with a 19g nozzle integrated in the stem which attaches to the end of a syringe. The intended use is as attached to the end of an irrigation syringe, during wound irrigation, to protect the user from (a) needlesticks (by eliminating the use of a needle), and (b) bloody splash during this procedure.

The *only* difference between the current device and the predicate device is the sterility level. Whereas the predicate device is marketed as a gamma-radiation-sterilized device, the current device is to be marketed as a clean, but unsterilized device. This is in response to requests from:

- (1) some end users (hospitals/physicians) who feel that an unsterilized Zerowet Splashield is adequate to irrigate a traumatic, already contaminated wound,
- (2) some end users (hospitals/physicians) who prefer a sterile product, but who wish to use in-house EtO sterilization facilities to sterilize the Zerowet Splashield as a component of a wound repair tray, and
- (3) independent kit packers who would like to include the unsterilized Zerowet Splashield as a component part of a disposable wound prep/repair tray, to be sterilized by a method of their choosing (either EtO or radiation), to then be marketed to end users (hospitals/physicians).

It is felt that there is *no substantial difference* in the integrity or performance of the Zerowet Splashield between the following four formats:

- 1) as a radiation sterilized device (as currently permitted by FDA),
- 2) as an unsterilized device, to be used as such,
- 3) as an unsterilized device, to be sterilized by the end user using in-house EtO,
- 4) as an unsterilized device, to be sterilized by a kit packer using EtO or radiation.

Although there is no body of literature comparing the use of sterilized versus unsterilized wound irrigation components, it is felt that there is no reasonable likelihood that the use of unsterilized components (as in the present submission) would adversely impact wound healing, wound infection rates, or general patient care. This is based on requests from a number of end users who are themselves specialists in the field of emergency wound care, who would prefer to use the Zerowet Splashield in an unsterilized format and feel that sterilization of this component for irrigation of a traumatic, contaminated wound is unnecessary.

Additionally, it is felt that sterilization by the end user or kit assembler using standard EtO or radiation protocols would not adversely affect the integrity or performance of this device.



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN 29 1998

Keith Stamler, MD
President
ZeroWet®, Incorporated
P.O. Box 4375
Palos Verdes Peninsula, California 90274

Re: K974288
Trade Name: ZeroWet Splashield
Regulatory Class: I
Product Code: KYZ
Dated: November 10, 1997
Received: November 14, 1997

Dear Dr. Stamler:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to 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). 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.

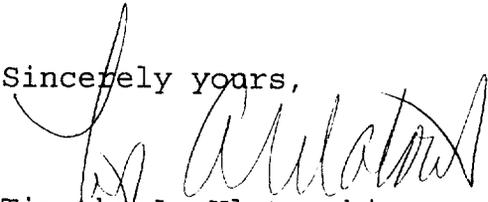
If your device is classified (see above) into either class II (Special Controls) or class III (Pre-market Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the current Good Manufacturing Practice requirement, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic (QS) inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does

not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its internet address "<http://www.fda.gov/cdrh/dsmamain.html>".

Sincerely yours,



Timothy A. Ulatowski
Director
Division of Dental, Infection Control
and General Hospital Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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510(k) Number (if known): K974288

Device Name: Zerowet Splashield

Indications For Use:

"The Zerowet Splashield is intended for use as an accessory to an irrigation syringe. It is intended to be attached to the end of said syringe during wound irrigation, in place of the commonly used needle, thereby eliminating the use of a needle during this procedure. Additionally, the Zerowet Splashield protects the user from contaminated (bloody) fluid splashing back during wound irrigation."

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Rafaela Ciccone

(Division Sign-Off)
Division of Dental, Infection Control,
and General Hospital Devices

510(k) Number K974288

Prescription Use
(Per 21 CFR 801.109)

OR

Over-The-Counter Use

(Optional Format 1-2-96)