

1K990936

PRE-MARKET NOTIFICATION: THE VAULT
510K SUMMARY

1. Identification of Applicant

- A. Company Name.....Stik Stoppers
- B. Applicants Name.....Darryl Crawford
President
- C. Street Address.....6 Hayden Bridge Way
Springfield, OR 97477
- D. Address of Manufacturing site.....Jenn Feng Electric Industrial Co.,LTD
OFFICE:NO.424 Fwushing Road
Taoyuan Taiwan, R O C
- E. Applicants Phone Numbers.....1-800-300-1989
Fax 208-265-6330
- F. Address of Sterilizing site.....N/A-Product is non-sterile
- G. Date of application.....March 10, 1999

2. Device

- A.Trade or proprietary Name.....The VAULT
- B. Common Name.....Sharps Container
- C. Classification Name.....Accessory to Hypodermic Single Lumen
Needle (CFR: 880.5570)
- D. Classification.....II
- E. Panel.....80
- F. Procodes.....FMI

3. General Description

The VAULT is a single-use , disposable , non-sterile, sharps transport container intended to be used in areas where larger sharps containers are not conveniently accessible, normally in the field use in paramedic and EMT jump kits. The Vaults design allows for easy one handed use by the EMT. Its function is to be available for portable sharps containment and as a alternative to using non-sharps containers or resheathing a needle with its original protective cover.

The VAULT is a 1.5x 5 inch box designed to set horizontally in a jump kit. The lid is designed to remain open until use and then permanently close for transportation of the contaminated sharps for safe disposal.

Each box is labeled with a biohazard label. The VAULT is also a bright red color to meet OSHA standards for warning of biohazard danger.

4. Substantial Equivalence

A. Predicate Devices for Stik Stoppers , The VAULT

Sharp-Safe 1.5 K955514
Sharps-a-Gator K964387
Sharp Shuttle K972279

B. Rationale Discussion

The side by side comparisons show the equivalence of all four products. All four are plastic , disposable, non-sterile, portable , sharps transport containers intended for point of use sharps disposal. All devices are puncture and leak resistant, one-handed sharps disposal units which offer a means of closure.

5.Design Features

- Impact Resistance.....The box was filled with needles and dropped from a height of 8 feet onto a concrete floor resulting in **NO** visible damage to box and **NO** needle ejection.
- Puncture Resistance.....Puncture resistance was tested by weighted pressure to needles on different box parts. Numerous tests resulted in the needles bending before they would puncture box. Pressure tested all parts of the box exceeded 7 lbs. of weight. These tests indicate the vault is very puncture resistant.
- Overfill Detection.....The box is designed with a horizontal opening in the top to allow easy sharps disposal and also overfill level detection. Sharps lay on there side allowing for user observation of contents.
- Leak Protection.....The sides and bottom of the box are a single molded piece designed not to leak. Water was added to the box to the top of the sides resulting in no leakage when kept in proper upright position.
- Sharps access and Closure.....The boxes lid is designed to close and not be reopened eliminating sharps access. Testing showed no visible access after closure if used following OSHA standards.
- Stability.....The box is designed to sit on a flat surface in an upright position. It fits easily into the top tray of a paramedic jump box and remains very stable.
- Locking Mechanism.....The VAULT has a one directional locking lid . It is not designed to be reopened after use.
- Handling.....The Vault is compact and easily transported after use. It can be placed in larger secondary sharps containers if necessary for easy transport to final disposal. Although it is safe to handle by itself.
- Capacity.....The vault was filled with liquid to determine volume of space in the box, test results indicated 3 ozs. . Sharps volume varied by the size and type of sharps used. The volume indicated sufficient space for a single use sharps container.



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

MAY 18 1999

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Mr. Darryl Crawford
President
Stik Stoppers, Incorporated
6 Hayden Bridge Way
Springfield, Oregon 97477

Re: K990936
Trade Name: The Vault
Regulatory Class: II
Product Code: FMI
Dated: March 8, 1999
Received: March 19, 1999

Dear Mr. Crawford:

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.

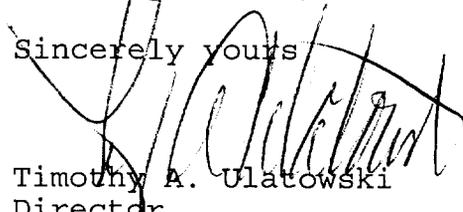
If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Good Manufacturing Practice for Medical Devices: General (GMP) regulation (21 CFR Part 820) and that, through periodic GMP 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.

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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) 594-4692. 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

510(k) Number (if known) K990936

Device Name : THE VAULT

Indications For Use:

The Vault is a single-use, disposable, non-sterile sharps transport container intended to be used by Paramedics and EMT's in their medical jump kits where larger sharps containers are not conveniently accessible. Its function is to be available for portable sharps containment as an alternative to using non-sharps containers or resheathing a needle with its original protective cover.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Chin S. Lam

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

510(k) Number K990936

Prescription Use _____
(Per 21 CFR 801.109)

OR

Over-The-Counter Use X

(Optional Format 1-2-96)