TZ Medical, Inc.
Madalyn C. Duncan
Regulatory Affairs/Quality Assurance Specialist
7272 S.W. Durham Road, #800
Portland, Oregon 97724

June 11, 2023

Re: K040208
Trade/Device Name: Neptune Products
Regulatory Class: Unclassified
Product Code: QSY

Dear Madalyn C. Duncan:

The Food and Drug Administration (FDA) is sending this letter to notify you of an administrative change related to your previous substantial equivalence (SE) determination letter dated May 11, 2004. Specifically, FDA is updating this SE Letter because FDA has better categorized your device technology under product code QSY.

Please note that the 510(k) submission was not re-reviewed. For questions regarding this letter please contact Julie Morabito, OHT4: Office of Surgical and Infection Control Devices, 240-402-3839, Julie.Morabito@fda.hhs.gov.

Sincerely,

Julie A. Morabito -S

Julie Morabito, Ph.D.
Assistant Director
DHT4B: Division of Infection Control and Plastic Surgery Devices
OHT4: Office of Surgical and Infection Control Devices
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAY 11 2004

Ms. Madalyn C. Duncan
Regulatory Affairs/Quality Assurance
TZ Medical, Inc.
7272 S.W. Durham Road, #800
Portland, Oregon 97724

Re: K040208
Trade/Device Name: Neptune Products
Regulatory Class: Unclassified
Product Code: FRO
Dated: April 22, 2004
Received: April 27, 2004

Dear Ms. Duncan:

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 Office of Compliance at (301) 594-4659. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Miriam C. Provost

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K040208

Device Name: Neptune Products

Indications For Use:

Neptune Pad (calcium alginate pad alone): Neptune Pad is used to promote the rapid control of bleeding and provide hemostasis for lacerations, abrasions, vascular access sites and following surgical incision. It can be used to achieve hemostasis at the skin surface for arterial/venous catheterization/tubes, needle puncture, hemodialysis and in patients on anticoagulation therapy.

Neptune Comfort-Band (Pressure Band with calcium alginate pad): Neptune Comfort-Band is used to provide pressure and promote the rapid control of bleeding and promote hemostasis following needle puncture, arterial/venous catheterization and access sites, including patients on anticoagulation therapy, and following hemodialysis.

Comfort-Band (Pressure Band alone): Comfort-Band is used to provide pressure and promote the rapid control of bleeding and hemostasis following needle puncture, arterial/venous catheterization and access sites, including patients on anticoagulation therapy, and following hemodialysis. It may be used alone, with Neptune Pad, with sterile gauze or other sterile wound dressings.

Prescription Use X AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mhorvath

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

510(k) Number K040208

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MAY 11 2004

510(k) SUMMARY of Safety and Effectiveness

(Persuant to 21 CFR 807.92)

I. GENERAL

A.	**Submitted By**:	TZ Medical Inc. 7272 S.W. Durham Road #800 Portland, Oregon 97724
B.	**Contact Person**	Madalyn C. Duncan Regulatory Affairs/ Quality Assurance Specialist
C.	**Proprietary Name**:	Neptune Pad Neptune Comfort-Band Comfort-Band
D.	**Classification Name**:	Unknown
E.	**Classification:**	Unclassified

II. DEVICE INFORMATION SUMMARY

A. Predicate Device

Kalginate by DeRoyal	(K941176)
HemoBand (originally manufactured for Innovations for Access by TZ Medical)	(K920614)
Chito-Seal by Perclose	(K021062)
Syvek Patch by Marine Polymer Technology	(K984177)

C. Device Description

Neptune Pad – Varying size, packaged sterile pads may be used alone as a wound dressing. The Pad may also be used with manual pressure or FDA cleared mechanical pressure devices to provide rapid control of bleeding and hemostasisat the skin surface.

Neptune Comfort-Band – The Comfort-Band is packaged with a Neptune Pad, and sterilized. It is strapped around the arm (hemodialysis graft, or radial/brachial arteries) to provide pressure for rapid control of bleeding and hemostasis.

Comfort-Band - The Comfort-Band is provided sterile or non-sterile, single use only. Non-sterile Comfort-Bands are provided with cleaning and high level disinfectant instructions) The Sterile Comfort-Band is packaged

alone and EtO sterilized. The Comfort-Bands may be used with or without a dressing. The device is strapped around the arm (hemodialysis graft, or radial/brachial arteries) to provide rapid pressure control of bleeding and hemostasis.

B. Device Intended Use

Neptune products are used to promote the rapid control of bleeding and hemostasis for wounds, the skin surface at arterial/vascular sites and in patients on anticoagulation therapy.

III. SUBSTANTIAL EQUIVQALENCE TESTING SUMMARY

The TZ Medical Neptune products have been tested and are considered safe and effective. With the exception of the Comfort-Band material and an adhesive interface between the Comfort-Band and calcium alginate pad, all other products and processes are identical to products with current 510(k)s K920614, and K941176). Testing and support data are on file. Data demonstrates there are no new risks associated with the product.