K081047

Non-Confidential Summary of Safety and Effectiveness

APR 29 2008

Submitter:	Dornoch Medical Systems Inc. 4032 West Riverside St. Riverside, MO 64150
Contact Person:	Anthony Martini Staff Engineer (816) 916-8458 Phone (816) 505-1050 Fax Email: amartini@dornoch.com
Date Prepared:	03/13/2008
Trade Name:	Transposal Ultra System consists of two major components. First, a cylinder suction cart and second a disposal & cleaning unit. Three models of the cylinder suction cart will be commercially distributed along with one canister suction unit. The Transposal Ultra Powered Roll Stand is identical in its operation except reusable canisters are used in place of the cylinders. • Transposal Ultra Cart System with: o Transposal Ultra Quad Cart – 52 liter volume – four cylinders o Transposal Ultra Duo Cart – 33 liter volume – two cylinders o Transposal Ultra Duo Cart – 26 liter volume – two cylinders o Transposal Ultra Evac – removal and cleaning unit. • Transposal Ultra Roll Stand: Transposal Ultra Powered Roll Stand – holds up to four 2.8 liter reusable canisters.
Classification:	Class II Apparatus, suction, ward use, portable, ac-powered 21 CFR 878.4780
Product Code:	JCX
Predicate Device(s):	The subject device is equivalent to the following devices: o Steris – SafeCycle 40 – exempt (GCX) o Product & Educational Services – Model 2300 general purpose suction pump – K941527 (JCX) o American Immuno Tech (Stryker) Neptune Waste Management System Rover – K990037 (FYD) o Stryker – Neptune Waste Management Systems – K012991 (FYD)

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Device Description:	The Transposal Ultra System (Ultra System) collects and disposes of waste fluids produced through surgical procedures. The Ultra System is a closed, self contained, reusable suction system. The Ultra Cart System can simultaneously collect fluids from up to four sources without mixing of the fluids. The Ultra Cart System is composed of two pieces of equipment the Transposal Ultra Cart (suction cylinder unit) and the Transposal Ultra Evac (removal and cleaning unit). The Ultra Carts can be used until 52L of fluids are collected. Once full, the Ultra Cart is attached to the Ultra Evac for automatic disposal into the hospital sanitary sewer and cleaning of the reservoir cylinders. Upon completion of the cleaning process, the cylinder lids are then replaced and the Ultra Cart is ready for use. The Transposal Ultra Roll Stand consists of a vacuum system and up to four reusable canisters. The fluid can be collected in each canister until 2.8L of fluids are collected. The canisters are then transported to the Transposal Safety Station where they are emptied and cleaned.
Intended Use:	The Dornoch Transposal Ultra System is self-powered suction / vacuum pump intended to collect and dispose of liquid waste within Hospital Operating Rooms, Pathology Labs, Surgical Outpatient Centers, and Doctor's Offices.
Functional and Safety Testing:	To verify that device design has meet the functional and performance requirements representative samples of the device underwent electrical, mechanical, software, and functional testing in accordance with IEC-60601-1, IEC-60601-1-1, IEC-60601-1-2, IEC-60529, ISO 10079-1 and ISO 10079-3.
Conclusion:	Dornoch Medical Systems Inc. considers the Transposal Ultra System to be equivalent to the predicate device listed above. This conclusion is based upon the devices' similarities in principles of operation, technology, materials and indications for use.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Dornoch Medical systems, Inc.
% Intertek Testing Services
Mr. Daniel W. Lehtonen
2307 East Aurora Road, Unit B7
Twinsburg, Ohio 44087

APR 29 2008

Re: K081047
Trade/Device Name: Transposal Ultra System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered suction pump
Regulatory Class: II
Product Code: JCX
Dated: April 10, 2008
Received: April 14, 2008

Dear Mr. Lehtonen:

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 Center for Devices and Radiological Health's (CDRH's) Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at (240) 276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at (240) 276-3464. 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 (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Indications for Use Statement

510(k) Number: K081047 (To be assigned)

Device Name: Transposal Ultra Systems

Indications for Use:

The Dornoch Transposal Ultra System is self-powered suction / vacuum pump intended to collect and dispose of liquid waste within Hospital Operating Rooms, Pathology Labs, Surgical Outpatient Centers, and Doctor's Offices.

Prescription Use **XX** (Part 21 CFR 801 Subpart D	AND/OR	Over-The-Counter Use ____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Neil R Ogden for MKM

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

510(k) Number K081047