DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
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Silver Spring, MD 20993-0002

December 21, 2016

Dornoch Medical Systems
Michael Wolford
Product Development Manager
200 NW Parkway
Riverside, Missouri 64150

Re: K162421
Trade/Device Name: IntelliCart™ System
Regulation Number: 21 CFR 878.4780
Regulation Name: Powered Suction Pump
Regulatory Class: Class II
Product Code: JCX
Dated: December 6, 2016
Received: December 7, 2016

Dear Michael Wolford:

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 contact the Division of Industry and Consumer Education 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. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 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 Industry and Consumer Education 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,

Michael J. Ryan -S

for Tina Kiang, Ph.D.
Acting Director
Division of Anesthesiology,
General Hospital, Respiratory,
Infection Control, and Dental Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

# Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: January 31, 2017
*See PRA Statement below.*

510(k) Number *(if known)*
N/A

Device Name

IntelliCartTM System

Indications for Use *(Describe)*

The IntelliCartTM System is a 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.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

**CONTINUE ON A SEPARATE PAGE IF NEEDED.**

This section applies only to requirements of the Paperwork Reduction Act of 1995.

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# 510(k) Summary

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|---|---|---|
| **510(k) Summary** | **Sponsor:** | Dornoch Medical Systems, Inc.<br>200 North West Parkway<br>Riverside, MO 64150<br>Establishment Registration Number: 1954182 |
| | **Contact:** | Michael T. Wolford<br>Regulatory Affairs Specialist<br>Phone: (330) 364-9411 |
| | **Date:** | 12/19/2016 |
| | **Trade Name:** | *IntelliCart™ System* |
| | **FDA Product Code/Device Common Name:** | JCX – Apparatus, Suction, Ward Use, Portable, Ac-Powered |
| | **Regulation Number and Description; Device Classification:** | 21 CFR 878.4780 – Powered suction pump; Class II |
| | **Predicate Device** | *Dornoch Ultra Suction Cart and Evac (K133786)* |
| | **Device Description** | The IntelliCartTM System is a 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.<br><br>The IntelliCartTM System (System) consists of a Fluid Cart (Cart) and Evac Station (Evac).<br><br>Carts are mobile devices used during surgery to collect patient fluids. Evacs are stationary devices used to process and clean Carts. The System's closed design significantly reduces employee exposure to potentially infectious surgical fluids, while eliminating up to 70% of operating room red bag waste.<br><br>Carts are equipped with large volume fluid reservoirs, a single regulated vacuum pump, and a height-adjustable IV pole. A single-use manifold (REF 00-5140-201-00) serves as the interface between a Cart's fluid reservoir and sterile patient suction tubing. A Cart model equipped with a bracket to hold a Smoke Evacuator is also available. |
| | **Intended Use:** | The *IntelliCart™ System* is a 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. |
| | **Technological Characteristics** | The *IntelliCart™ System* is a closed self-powered suction device providing various levels of suction, as selected by the user, ranging from 0-600 mmHg at maximum flow volume, and collection of up to 34L of liquid surgical |

waste into cart canisters equipped with a viewing window for display of canister contents shown in 100ml increments. The suction cart is portable, equipped with caster type wheels with a profile able to pass through 36 inch minimum wide doorways and allows for connection to a standard 120V/60Hz/15A facility power supply and connection to facility wall suction when necessary. Cart Canisters are integrated with a window tint feature that visually restricts canister contents during transport.

The *IntelliCart™ System* is operated using a back lit LCD touch screen display monitor equipped with lateral adjustment capabilities and provides digital display confirmation of total fluid capacity used as well as a functional interface for suction selection/adjustment and cart cleaning.

Single use manifolds are equipped with hydrophobic filters which turn color after wash cycle is completed, giving visual indication of a manifold which must be discarded.

The Evac Station is equipped with a coupler that connects to the Suction Cart and, using compatible bleach and enzymatic solutions to break down solid waste, empties and cleans cart canisters. After emptying and cleaning cart canisters, the Evac Station allows for draining surgical waste into facility drains.

The *IntelliCart™ System* can be equipped with a powered or manual IV pole, supporting up to 12,000mL of bagged fluid and allows mounting of a compatible smoke evacuation device.

**Comparison to Predicate:**

The *IntelliCart™ System* is substantially equivalent to the legally marketed predicate device, *Dornoch Ultra Suction Cart and Evac*, in that these devices have the same intended use, materials and are similar in design. The following tables provide a comparison between the predicate device and modified device showing similarities and differences:

**System Use**

| Property | Predicate Device (Ultra Suction Cart and Evac K133786) | Modified Device (IntelliCart™ System) |
|---|---|---|
| **Intended Use** | The Transposal Ultra Suction Cart and Evac is a 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. | The *IntelliCart™ System* is a 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. |
| **Single Use or Reusable** | Cart, Evac – Reusable<br>Manifold, Single Use | Same |
| **Target Population** | Ward Use, General Surgical Application | Same |

**System Operating Principle**

| Property | Predicate Device (Ultra Suction Cart and Evac K133786) | Modified Device (IntelliCart™ System) |
|---|---|---|
| **Display** | LCD, Backlit Touch | Same |
| **Suction/Exhaust** | Closed suction system with variable suction levels based on user selection providing regulated vacuum from 0-600mmHg using AC powered twin piston vacuum pump passing through single use manifolds and into canisters. | Same |
| **Filtration** | HEPA Filtration 99.97% | Same |
| **Cleaning** | Cart Canister Processing using automated validated cycle | Same |
| **Manifold** | Single Use, disposable manifold with Hydrophobic Filter | Same |
| **Software** | Validated Software | Same |
| **Electrical Requirements** | **(Cart)** 120VAC, 60Hz, 4.5amp<br>**(Evac)** 120VAC, 60Hz, 8amp | **(Cart)** 120VAC, 60Hz, 4.75amp<br>**(Evac)** Same |
| **Portable** | Locking casters and push handle allow cart to be easily moved | Same |

**System Design**

| Property | Predicate Device (Ultra Suction Cart and Evac K133786) | Modified Device (IntelliCart™ System) |
|---|---|---|
| **Materials** | No direct or indirect patient contact | Same |
| **Touch Screen** | LCD backlit color touch screen display | Same |

| | | |
|---|---|---|
| **Total Fluid Capacity** | Minimum 33L | 34L |
| **Single Use Manifold** | Manifold hydrophobic filter turns blue after use, indicating it must be replaced | Same |
| **Suction Range** | 0-600mmHg | Same |
| **Footprint** | 55”H x 24”W x 24”D | 55”H x 23.5”W x 23”D |
| **Safety Alert** | Audible and visual display for early warning of overflow protection system and vacuum start up alert | Same |
| **Compatible with Wall Suction** | Yes | Same |
| **ConSeal™ Tint** | Not Available | Available |
| **Canister Exterior Graduations** | Graduations marked on canister exterior provide approximate visual indication of contents in 100mL increments. | Same |
| **IV Pole** | Carts available with powered or manual IV pole, capable of 12,000mL maximum fluid capacity | Same |
| **External Mounting of compatible smoke evacuation** | Yes | Yes |
| **HEPA Filtration** | 99.97% | Same |
| **Cleaning** | Multiple user selected Enzymatic and Bleach cleaning cycles from 3-12 minutes | Same |
| **Safety Features** | | |
| **Feature** | **Predicate Device (Ultra Suction Cart and Evac K133786)** | **Modified Device (IntelliCart™ System)** |
| **Closed System Design** | Confine and contain fluids during collection and disposal | Same |
| **Interactive Controls** | Graphical User Interface (GUI) guides user through system operation | Same |
| **Bleach Cycle Monitoring** | Continuous automatic monitoring of bleach cycle using electronic sensors | Same |
| **Fluid Backflow Protection** | Positive air gap maintained between collected fluids and single-use Manifolds | Same |

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| **Vacuum System Protection** | Hydrophobic filters shut off vacuum supply when wet, preventing liquids from contaminating the Cart vacuum supply | Same |
| **Air Exhaust Protection** | Replaceable HEPA rated filter | Same |
| **Overflow Protection** | Warning to alert user when reservoir is 1000mL automatic shut off when canisters have reached full capacity | Warning to alert user when reservoir is 3000mL and 1500mL from full capacity – automatic shut off when canisters have reached full capacity |
| **ES 60601-1 Classification** | Class 1, Type B applied part (suction tubing – not supplied by Zimmer Biomet) | Same |

**Non-Clinical Performance Data as Compared with the Predicate Device**

The following performance standards were used in determining equivalent performance of the modified device:

| Standard or Test Type | Predetermined Acceptance Criteria | Results | |
|---|---|---|---|
| | | Predicate Device (Ultra Suction Cart and Evac K133786) | Modified Device (IntelliCart™ System) |
| **IEC 60601-1** Medical electrical equipment - Part 1: General requirements for basic safety and essential performance | Yes | Pass | Pass |
| **IEC 60601-1-2** Medical electrical equipment - Part 1-2: General requirements for basic safety and essential performance - Collateral Standard: Electromagnetic disturbances - Requirements and Tests | Yes | Pass | Pass |
| **IEC 60601-1-6** Medical electrical equipment - Part 1-6: General requirements for basic safety and essential performance - Collateral standard: Usability | Yes | N/A | Pass |
| **ISO 10079-1** Medical suction equipment - Part 1: Electrically powered suction equipment | Yes | Pass | Pass |
| **ISO 10993-1** Biological evaluation of medical devices - Part 1: Evaluation and testing within a risk management process | Not required – no direct or indirect patient contact | N/A | N/A |

**Electrical Safety, Electromagnetic compatibility (EMC)**

Medical device safety testing was conducted in accordance with IEC 60601-1 standard for safety, IEC 60601-1-2 standard for EMC. Human factors were also considered in the design of the IntelliCart™ System and testing was performed in accordance with IEC 60601-1-6 and Applying Human Factors and Usability Engineering to Optimize Medical Device Design, Guidance for Industry and Food and Drug Administration Staff, February 3, 2016. Critical and essential tasks were identified as part of the studies. All identified issues were managed and mitigated to an acceptable level. The IntelliCart™ System passed all electrical safety, and electromagnetic compatibility tests to predetermined acceptance criteria.

**Software and Display Verification and Validation**

Software verification and validation were performed at a systems and unit level and information supplied in accordance with guidance as recommended by FDA Guidance for Industry "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices". Software passed all predetermined acceptance criteria including reservoir overflow protection, cart reservoir processing using validated cycles, watchdog safety transducer and safety start up warning screen.

**Mechanical Verification and Validation**

**Suction Performance**

The IntelliCart™ System suction performance was designed and evaluated according to ISO 10079-1 Electrically powered suction equipment and as recommended by FDA "Guidance for Industry and FDA Reviewers/Staff: Guidance Document for Powered Suction Pump 510(k)s". All critical and essential tasks were identified and mitigated through risk analysis to an acceptable level.

The IntelliCart™ System was evaluated to provide adjustable vacuum pressure as measured at the manifold port to predetermined acceptance criteria to demonstrate operation capable of providing adjustable vacuum up to 12 hours of continuous use at 600mmHg.

**Safety Features**

The IntelliCart™ System was tested to predetermined acceptance criteria for Closed System Design, Interactive controls including de-bounce feature, Fluid Backflow Protection, Watchdog Safety Transducer, Wash Fluid leak free seals around covers and manifolds, and User Interface Vacuum Start Up Warning. The IntelliCart™ System met all predetermined acceptance criteria with passing results.

The IntelliCart™ fluid path was tested to predetermined acceptance criteria for chemical resistance against compatible enzymatic cleaners, bleach and Bactisure™. The IntelliCart™ met all predetermined acceptance criteria with passing results.

The IntelliCart™ System disposable manifold was tested to predetermined acceptance criteria to provide vacuum seal in the reservoir when installed. The IntelliCart™ met all acceptance criteria with passing results.

**IV Pole Function and Support**

Manual and Power IV Poles were tested to predetermined acceptance criteria for maximum bagged fluid support and automatic function (power IV pole only). The IntelliCart™ met all acceptance criteria with passing results.

**Outer Body Shell and Fluid Capacity**

The IntelliCart™ was tested to predetermined acceptance criteria for portability using casters and brakes including profile requirements to pass through standard 36" door thresholds. The IntelliCart™ met all acceptance criteria with passing results.

IntelliCart™ was tested to predetermined acceptance criteria to include directly viewable fluid measurements, easily viewable touchscreen monitor and exterior surfaces which provide chemical resistance to standard hospital wipes. The IntelliCart™ met all acceptance criteria with passing results.

**Fluid Reservoir Concealment**

ConSeal™ technology providing concealment of canister contents was evaluated to predetermined acceptance criteria for the concealment of collected waste fluid. The IntelliCart™ met all acceptance criteria with passing results.

**Conclusion**

The subject device is substantially equivalent to the predicate device.