K031997

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510(k) Summary
MALLINCKRODT DAR S.r.l.
Ty-Care™ / Ty-Care™ exel Closed Suction System
(per 21 CFR 807.92)

1. SPONSOR/APPLICANT NAME, ADDRESS, TELEPHONE NUMBER

MALLINCKRODT DAR S.R.L.
via G. Bove, 2/4/6/8
I-41037 Mirandola (MODENA), ITALY

Contact Person: Giuseppe Tomasini
Telephone: 011 39 0535 617922
(E-mail: giuseppe.tomasini@mkg.com.)

Date of Summary Preparation: June 26, 2003

2. DEVICE NAME

Proprietary Name:	MALLINCKRODT DAR Ty-Care™ / Ty-Care™ exel Closed Suction System
Common/Usual Name:	In-line closed suction system
Classification Name:	Tracheobronchial suction catheter (73) BSY Class I (General Control) 21 CFR 868.6810

3. IDENTIFICATION OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) TO WHICH EQUIVALENCE IS BEING CLAIMED

MALLINCKRODT DAR HI-CARE (K972258)

Ballard (Kimberly Clark) Trach-Care (K974630, K964369, K873810)

4. DEVICE DESCRIPTION

Ty-Care is a suction catheter system that is designed to connect to the endotracheal tube or tracheostomy tube of the patient and remains in place up to 48 hours ("fixed" version). Ty-Care exel is a detachable system and features a suction catheter that must be replaced after 24 hours while the angled connector (elbow) may be replaced

after 72 hours of use. If the patient is on mechanical ventilation, this device allows the attending health professional to suction the patient's tracheobronchial secretions without disconnecting the ventilator. Ty-Care exel offers all the advantages of Ty-Care system with the added feature of a rotating patient-access valve.

5. INTENDED USE/INDICATIONS FOR USE

The Ty-Care/Ty-Care exel Closed Suction System is intended for endotracheal / tracheostomy suction of adult and pediatric intubated patients (including neonates). This device is intended for single use only.

6. A STATEMENT OF HOW THE TECHNOLOGICAL CHARACTERISTICS OF THE DEVICE COMPARE TO THOSE OF THE PREDICATE OR LEGALLY MARKETED DEVICE(S) CITED

MALLINCKRODT DAR S.R.L. makes the claim of substantial equivalence with the H-Care based on intended use, design, operational characteristics, and materials of construction. A side-by-side comparison of the MALLINCKRODT DAR Ty-Care™ / Ty-Care™ exel Closed Suction System to the systems cited is provided in Table H-1 below.

Table H-1. Comparison of the Ty-Care™/Ty-Care™ exel Closed Suction System with Predicate Devices

		MALLINCKRODT DAR Ty-Care™ / Ty-Care™ exel	MALLINCKRODT DAR Hi-Care	BALLARD TRACH-CARE
510(k) number		Proposed	K972258	K974630 K964369 K873810
Characteristics	Closed System	YES	YES	YES
	Indicated for single patient use	YES	YES	YES
	Labeled for replacement after 24 hours	NO*	YES	NO
	Allows catheter replacement without disconnecting patient from ventilator	YES**	YES	NO
	Allows suctioning without disconnecting patient from ventilator	YES	YES	YES
	Manual control of vacuum	YES	YES	YES
	Standard ISO connectors	YES	YES	YES
	Translucent catheter body	YES	YES	YES
	Clear plastic sleeve covering catheter body	YES	YES	YES
	Irrigation port	YES	YES	Not specified
	Rotating patient access valve	YES**	YES	NO
	Double swivel elbow (DSE)	YES	NO	YES
Sterility	Sterile	YES	YES	YES
Design	Available in adult (ADT), pediatric (PED), and Neonatal (INF)	YES	YES	Not specified

* *For the Ty-Care™ ("fixed" version), the complete system shall be replaced after 48 hours (as the related IFU clearly states). The Ty-Care™ exel (detachable system) features a suction catheter that should be replaced after 24 hours while the elbow and other components are replaced after 72 hours. The Hi-Care suction catheter maximum use is 24 hours, as stated in the related Instructions for Use.*

** *Available only for the Ty-Care™ exel version.*

7. TESTING

Biocompatibility and performance testing demonstrate that MALLINCKRODT DAR Ty-Care™ / Ty-Care Closed Suction System complies with designated voluntary standards and fulfills product specifications. Verification and validation testing demonstrates that the increased duration of use raises no new issues of safety or effectiveness.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 25 2003

Mr. Giuseppe Tomasini
Regulatory Affairs & Quality System Manager
Mallinckrodt DAR, S.R.L.
Via Giacomo Bove, 2/4/6/8
Mirandola (Modena) I-41037
ITALY

Re: K031997
Trade/Device Name: Mallinckrodt DAR S.RL. Ty-Care / Ty-Care Exel Closed Suction System
Regulation Number: 868.6810
Regulation Name: Tracheobronchial Suction Catheter
Regulatory Class: I
Product Code: BSY
Dated: October 16, 2003
Received: October 17, 2003

Dear Mr. Tomasini:

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.

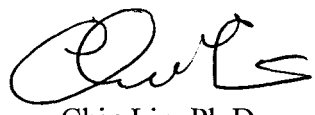
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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) 594-4646. 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,



Chiu Lin, Ph.D.
Director
Division of Anesthesiology, General Hospital,
Infection Control and Dental Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known):

General Information

Device Name: MALLINCKRODT DAR Ty-Care™ and Ty-Care™ exel Closed Suction System

Indications for Use:

This closed suction system is indicated for endotracheal / tracheostomy suction of adult and pediatric intubated patients (including neonates). This device is intended for single use only.

(PLEASE DO NOT WRITE BELOW THIS LINE — CONTINUE ON ANOTHER PAGE IF NECESSARY)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number: K031997

Prescription Use ✓ OR Over-The-Counter Use ____
(Per 21 CFR 801.109)