Swiss Medical Care

K062265

510(k) SUMMARY
SWISS MEDICAL CARE S.A.
CT EXPRÉS III™ CONTRAST MEDIA DELIVERY SYSTEM
(PER 21 CFR 807.92)

1. SUBMITTER NAME AND ADDRESS

DEC 26 2006

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2. DEVICE NAME

Trade Name:	CT Exprés III™ Contrast Media Delivery System (CMDS)
Common/Usual Name:	Automatic injector for contrast media Injector
Classification Name:	Injector, Contrast medium, automatic (21 CFR 870.1650, Product Code IZQ)

3. PREDICATE DEVICE/S

Premica™-CT Contrast Media Delivery System – K983314

4. DEVICE DESCRIPTION

The CT Exprés III™ Contrast Media Delivery System (CMDS) is a programmable, software driven, electromechanical, high-pressure contrast media injection system.

The positive pressure necessary for the injection is generated by a disposable rotary peristaltic cassette, located inside one of the disposable (Patient Set).

The CT Exprés III™ Contrast Media Delivery System consists of the main following elements:

- The instrument, i.e. the main unit (injector unit and power supply), the main control panel, and associated cables.
- Accessories, i.e. the handswitch.
- Detachable parts, i.e. the remote control panel, the bottle insulators, and the pedestal pole.
- Three associated proprietary disposables creating a complete fluidic pathway from the bottle of CM to the patient, i.e. the "Bottle Spike", the "Day Set III" and the "Patient Set".

The printer and ceiling mount are provided as optional devices for use in combination with the CT Exprés III™.

5. INTENDED USE

The CT Exprés III™ Contrast Media Delivery System (CMDS) is indicated for controlled automatic administration, on the venous side, of contrast media (CM) to human subjects while undergoing examination by means of a computed tomography (CT) scanner.

The system consists of the CT Exprés III™ Instrument, the Bottle Spike, the Day Set III, the Patient Set, accessories and detachable parts.

This device is not intended for injection of CM for coronary arteriography, or for any other use for which the device is not indicated.
This device is only to be operated by and under quasi-continuous supervision of qualified medical staff in an appropriate licensed health care facility.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

Information supplied in this premarket notification includes descriptive information about the intended use, operation, and technological characteristics. A side-by-side comparison of the CT Exprés III™ Contrast Media Delivery System with the CT Exprés™ Contrast Media Delivery System is provided in Table J-1 below:

Table H-1: Comparison of CT Exprés III™ Contrast Media Delivery System with CT Exprés™ Contrast Media Delivery System

Characteristics	CT Exprés III™ CMDS	Premica™-CT CMDS (K983314)
Indication		
Indicated for controlled administration of contrast media for computed tomography scans	Yes	Yes
Not intended for use with children under 16 years of age	No	Yes
Physical Design		
Remote panel	Yes	Yes
Weight (without fluid containers)	Injector : 8.5 kg (18 lbs) Console : 1.7 kg (3.7 lbs)	Injector : 8 kg (17.6 lbs) Console : 1.7 kg (lbs)
Contrast media temperature control	Bottle insulators	Bottle insulators
Single patient use disposables	Patient Set	Patient Set
Multiple patient solutions	Yes	Yes
Designed to prevent reuse of disposables	Yes	Yes
Operational Characteristics		
Programmable flow rate	0.5 – 9.9 mL/s	0.2 – 9.9 mL/s
Programmable injection volume per injection	0 – 300 mL	0 – 300 mL
Maximum injection duration	9 min 59 sec	9 min 59 sec

Table H-1: Comparison of CT Exprés III™ Contrast Media Delivery System with CT Exprés™ Contrast Media Delivery System
(Continued)

Characteristics	CT Exprés III™ CMDS	Premica™-CT CMDS (K983314)
Contrast media container volume	50-500 mL	50-500 mL
Pressure limit	8 bar (ca. 120 psi)	8 bar (ca. 120 psi)
Test injection default	Yes	Yes
Injection capabilities	Up to 3 phases	Up to 5 phases
Saline flush	Yes	Yes
Connecting tubing	Length = 1.5 m	Length = 1.5 m
Access types	Flexible	Flexible
Access gauge	16-27 G	16-22 G
Interphase delay	0-99 sec	0-99 sec
Scan delay	0-99 sec	0-99 sec
Injection protocol storage	100 protocols	100 protocols

Indications for use

Both the CT Exprés III™ and Premica™-CT contrast media delivery system are indicated for the controlled administration of contrast media for computed tomography scans.

The CT Exprés III™ can be used with all patients. The Premica™-CT labelling indicates that the device can not be used with patients under 16 years of age.

Physical design

Both systems consist of several elements.

Both systems have remote panels to allow easier user control of the systems.

Both systems provide single patient use disposables ("Patient Set").
Both systems have disposables with design features that prevent their reuse.

Both systems draw their contrast media or saline from multi-dose containers (bottles or soft pouches). Contrast media container volumes are identical for the two systems (50 – 500 mL).

Operational characteristics

Programmable flow rate ranges are nearly identical for both systems (0.5 – 9.9 mL/s for the CT Exprés III™, 0.2-9.9 mL/s).

The programmable volume of contrast media per injection is also identical (0 – 300 mL/injection).

Programmable flow rate ranges and programmable volume ranges being identical, the injection durations are also identical for the two systems.

The CT Exprés III™ can be programmed for injection sequences of one to five steps:
1. Saline (pre-flush)
2. Contrast media (phase one)
3. Saline (intermediate flush)
4. Contrast media (phase two)
5. Saline (post-flush)

The Premica™-CT can be programmed for injection sequences of up to three steps:
1. Contrast media (phase one)
2. Contrast media (phase two)
3. Saline (post-flush)

Both systems incorporate pressure sensors with the limit for triggering a pressure alarm (occlusion alarm) at 8 bar (*ca.* 120 psi).

Both systems incorporate Air-In-Line sensors for patient safety.

Since contrast media temperature can change the fluid viscosity, both systems provide for passive temperature control in the form of bottle insulators to reduce temperature loss from the heated contrast.

One difference between the two systems is the ability of the CT Exprés III™ to simultaneously accommodate two bottles of contrast media and one container with saline, whereas the Premica™-CT can accommodate only two fluid containers (two bottles of contrast media OR one bottle with contrast media and one container with saline).

Another difference between the two systems is the ability of the CT Exprés III™ to accept not only the range of needle sizes (16-22 G) normally used for injecting contrast media, but also very small needle sizes (23–27 G). Note that, when using the very small needle sizes (23-27 G), the programmable injection rates may be limited to values of only a few mL/s because the injection pressure that CT Exprés III™ is generating is limited to 8 bar (ca. 120 psi). As a safety feature, CT Exprés III™ will automatically display information for the user when an injection rate is programmed above the limit injection rate. Under these circumstances, the CT Exprés III™ will not function. This makes the CT Exprés III™ suitable for use with patients or injection conditions where very small needle sizes are preferred.

The Premica™-CT can only accept needle sizes in the range of 16 – 22 G, making it unsuitable for use with patients or injection conditions where very small needle sizes are preferred.

These differences are explained for in the CT Exprés III™ operator's manual and software programming capabilities and do not raise any new questions of safety or effectiveness.

7. PREPARATION DATE OF 510(K) SUMMARY

July 26, 2006

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Swiss Medical Care S.A.
% Mr. Robert L. Aromando, Jr.
Managing Partner
K Street Associates, LLC
PMB 237, 203 Main Street
FLEMINGTON NJ 08822

DEC 26 2006

Re: K062265
Trade/Device Name: Swiss Medical Care S.A. CT EXPRESS III™ Contrast Media Delivery System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: II
Product Code: IZQ
Dated: December 7, 2006
Received: December 8, 2006

Dear Mr. Aromando:

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 (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 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 one of the following numbers, based on the regulation number at the top of this letter:

21 CFR 876.xxx	(Gastroenterology/Renal/Urology	240-276-0115
21 CFR 884.xxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 894.xxx	(Radiology)	240-276-0120
Other		240-276-0100

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 (240) 276-3150
or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

K062265

Indications for Use

510(k) Number (if known): K062265

Device Name: **SWISS MEDICAL CARE S.A. CT EXPRÉS III™ CONTRAST MEDIA DELIVERY SYSTEM**

Indications for Use:

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Prescription Use ___X___ (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)

Barbara Cuchwd for NCB

(Division Sign-Off)
Division of Reproductive, Abdominal, and Radiological Devices
510(k) Number K062265