



Food and Drug Administration
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January 22, 2016

Bracco Injeneering S.A.
% Cynthia Nolte
Senior Director, Regulatory Affairs
Icon Clinical Research LLC
62 Forest Street Suite 300
Marlborough, Massachusetts 01752

Re: K151048

Trade/Device Name: CT Exprès™ 3D Contrast Media Delivery System
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic Injector and Syringe
Regulatory Class: Class II
Product Code: IZQ
Dated: December 30, 2015
Received: December 31, 2015

Dear Cynthia Nolte:

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 yours,

Kenneth J. Cavanaugh -S

for

Bram D. Zuckerman, M.D.

Director

Division of Cardiovascular Devices

Office of Device Evaluation

Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known)

K151048

Device Name

CT Expres" 3D Contrast Media Delivery System

Indications for Use (Describe)

The CT Expres™ 3D Contrast Media Delivery System is indicated for controlled automatic administration, on the venous side, of contrast media and saline, to human subjects while undergoing examination by means of a computed tomography (CT) scanner.

The CT Expres™ 3D Contrast Media Delivery System is specifically indicated for use in CT procedures for the delivery of Isovue (Iopamidol Injection) contrast media as supplied in an Imaging Bulk Package (IBP), for a maximum of 20 bottles of contrast media or a maximum of ten (10) hours, whichever comes first, per Day Set III HP disposable. The Bottle Spike disposable is for single-bottle use only and must be discarded with the contrast media bottle. The Patient Set disposable must be discarded after each patient procedure.

The CT Expres™ 3D is to be used only by and under quasi-continuous supervision of trained health care professionals in an appropriate licensed health care facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent.

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)

PLEASE DO NOT WRITE BELOW THIS LINE – CONTINUE ON A SEPARATE PAGE IF NEEDED.

FOR FDA USE ONLY

Concurrence of Center for Devices and Radiological Health (CDRH) (Signature)

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K151048
510(k) Summary
for the Bracco Injengineering
CT Exprès™ 3D Contrast Media Delivery System
(per 21CFR 807. 92)

1. SUBMITTER/510(K) HOLDER

Bracco Injengineering S.A.
Avenue de Sévelin 46
CH - 1004 Lausanne, Switzerland

Contact Person: Maud Giorgi, Sr. Regulatory Affairs Manager

Telephone: +41 21 621 74 00

Date Prepared: January 21, 2016

2. DEVICE NAME

Proprietary Name: CT Exprès™ 3D Contrast Media Delivery System

Common/Usual Name: Automatic injector for contrast media

Classification Name: Injector, contrast medium, automatic

Regulation Description: Angiographic injector and syringe

3. PREDICATE DEVICE

CT Exprès III™ Contrast Media Delivery System, K062265 (Swiss Medical Care, S.A.)

4. DEVICE DESCRIPTION

The CT Exprès™ 3D Contrast Media Delivery System (CT Exprès™ 3D) is designed for the controlled, automatic administration, on the venous side, of water-soluble radiographic medical imaging products for contrast enhancement of computed tomography (CECT) imaging. The positive pressure necessary for the injection is generated by a rotary peristaltic pump that is part of the disposable Patient Set. The system is designed to protect the patient against air injection and occlusion by incorporating sensors to detect air and pressure within the fluid pathway.

The system consisting of the CT Exprès™ 3D injector unit, main and remote control panels, hand switch, bottle insulators, floor stand and disposables (Bottle Spike Type B, Day Set III *HP*, Patient Set), is specifically designed for the delivery of Isovue® (Iopamidol Injection) contrast media and saline. The Isovue® is supplied for use in the CT Exprès™ 3D System as an Imaging Bulk Package (IBP), for a maximum of 20 bottles of contrast media per Day Set III *HP* disposable or 10 hours, whichever comes first.

The CT Exprès™ 3D Contrast Media Delivery System is a combination product. As stated above, the CT Exprès™ 3D is specifically indicated for use in CT procedures for the delivery of Isovue (Iopamidol Injection) contrast media as supplied in an Imaging Bulk Package (IBP), (submitted in the supplemental New Drug Application sNDA to the Isovue NDA 20-327 (S011)).

5. INDICATION FOR USE/INTENDED USE

The CT Exprès™ 3D Contrast Media Delivery System is indicated for controlled automatic administration, on the venous side, of contrast media and saline, to human subjects while undergoing examination by means of a computed tomography (CT) scanner.

The CT Exprès™ 3D Contrast Media Delivery System is specifically indicated for use in CT procedures for the delivery of Isovue (Iopamidol Injection) contrast media as supplied in an Imaging Bulk Package (IBP), for a maximum of 20 bottles of contrast media or a maximum of ten (10) hours, whichever comes first, per Day Set III *HP* disposable. The Bottle Spike disposable is for single-bottle use only and must be discarded with the contrast media bottle. The Patient Set must be discarded after each patient procedure.

The CT Exprès™ 3D is to be used only by and under quasi-continuous supervision of trained health care professionals in an appropriate licensed health care facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent.

6. SUMMARY OF TECHNOLOGICAL CHARACTERISTICS COMPARED TO THE PREDICATE DEVICE

Both the CT Exprès™ 3D and predicate CT Exprès™ systems have identical overall designs. These systems consist of identical components (injector unit, main and remote control panels, hand switch, bottle insulator and Floor Stand). Both systems have similar weights and dimensions. Power requirements are identical for the two systems. The major design changes involve an upgrade to an LCD screen for the control panel interface and an increase in the number of programmable phases for an injection cycle to allow greater programming flexibility.

Both the CT Exprès™ 3D and predicate CT Exprès™ systems are used in conjunction with disposables that create a fluid pathway from the bottles of Contrast Media and the saline container to the patient. The fluid pathway of the systems is comprised of multipatient Bottle Spike Type B and a Day Set and a single patient use Patient Set. All of these disposables are designed to prevent reuse beyond their specified usage lifetime. The CT Exprès™ 3D and predicate disposables have identical functions, where the Patient Set connects the Day Set III *HP* to the patient and contains the rotary peristaltic pump cassette that generates the positive pressure necessary for the injection. The Day Set III *HP* connects the contrast media and

saline fluid containers to the Patient Set, and the Bottle Spike connects the bottle of contrast media to the Day Set III *HP*.

The difference in the disposables design is limited to the diameters of the contrast media tubing in the Day Set. The Day Set III *HP* (CT Exprès™ 3D) has a 4mm (inner) and 6mm (outer) diameter as compared to the predicate Day Set III (predicate) which has an inner diameter of 3mm and an outer diameter of 4.1mm. The larger diameter reduces fluid resistance and allows for an increase in maximal flow rate (but still within the maximal limit of the predicate).

Both systems are able to accept a similar range of needle sizes, including those normally used for injecting contrast media (16-22G), as well as needle sizes of up to 24G for the CT Exprès™ 3D and up to 27G for the CT Exprès III™, making both systems suitable for use with patients or injection conditions where small needle sizes are preferred.

Various small material changes have been made between the predicate and CT Exprès™ 3D Patient Set and Day Set III *HP*. The Bottle Spike Type B supplied with the two systems is identical.

7. SUMMARY OF NON-CLINICAL PERFORMANCE TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

Design verification and validation for the CT Exprès™ 3D Contrast Media Injection System was performed in accordance with the Master Design Verification and Validation Plan for the product. Specific testing conducted is listed below.

The disposables were tested to confirm biocompatibility (cytotoxicity, irritation, sensitization, acute systemic toxicity, hemocompatibility, pyrogenicity).

The CT Exprès™ main unit and accessories were tested to demonstrate conformance with established performance criteria:

- Electrical safety, electromagnetic interference/compatibility
- Software verification and validation
- Reliability
- Injection volume accuracy
- Air detection
- Occlusion
- Flow rate accuracy

The system validation tests listed below were performed to validate specific performance criteria and confirm that the CT Exprès™ 3D is safe for the indications for use:

- Sterilization validation
- Real time aging
- Packaging validation
- Transportation testing
- Cleaning/disinfection instructions
- Microbial ingress
- Cross-contamination
- Chemical compatibility
- Simulated use usability validation

8. SUMMARY OF CLINICAL TESTING AS BASIS FOR SUBSTANTIAL EQUIVALENCE

No clinical studies were performed using the CT Exprès™ 3D. Usability assessments were conducted in a simulated use environment to optimize the device design and support the safe use of the CT Exprès™ 3D Injector with the Isovue IBP and saline. The results demonstrated that users can operate the CT Exprès™ 3D as safely and as effectively as the predicate device.

9. SUMMARY OF OTHER INFORMATION

No other information is available.

10. CONCLUSIONS DRAWN FROM NON-CLINICAL AND CLINICAL TESTS

Extensive preclinical testing has been performed to verify and validate the safety and performance of the multi-patient CT Exprès™ 3D injector platform for the specific indications for use of Isovue® contrast media as supplied in an IBP and saline. With the exception of the disposables material changes for which additional biocompatibility testing was conducted, the technological characteristics and overall design of the CT Exprès™ 3D are essentially identical to those of the predicate device, with any differences limited to minor differences in design and performance that do not raise any new questions of safety or effectiveness.

Therefore, Bracco Injengineering considers the CT Exprès™ 3D to be substantially equivalent to the CT Exprés III™, subject of K062265. A side-by-side comparison of the predicate and subject devices is provided in Tables 1 and 2.

Table 1. Side-by-Side Comparison, System

Contrast Media Delivery	Subject Device	Predicate
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System	CT Exprès™ 3D	CT Exprès III™
Manufacturer	Bracco Injengineering S.A.	Swiss Medical Care
Regulatory Status	K151048	K062265
Indication		
Intended Use/Indications for Use	<p>The CT Exprès™ 3D Contrast Media Delivery System is indicated for the controlled automatic administration, on the venous side, of contrast media and saline, to human subjects while undergoing examination by means of a computed tomography (CT) scanner.</p> <p>The CT Exprès™ 3D Contrast Media Delivery System is specifically indicated for use in CT procedures for the delivery of Isovue (Iopamidol Injection) contrast media as supplied in an Imaging Bulk Package (IBP), for a maximum of 20 bottles of contrast media or a maximum of ten (10) hours, whichever comes first, per Day Set III <i>HP</i> disposable. The Bottle Spike disposable is for single-bottle use only and must be discarded with the contrast media bottle. The Patient Set disposable must be discarded after each patient procedure.</p> <p>The CT Exprès™ 3D is to be used only by and under quasi-continuous supervision of trained health care professionals in an appropriate licensed health care facility, in a room designated for radiological procedures that involve intravascular administration of a contrast agent.</p>	<p>The CT Exprès 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 computed tomography (CT) scanner.</p> <p>The system consists of the CT Exprès III™ Instrument, the Bottle Spike, the Day Set III, the Patient Set, accessories and detachable parts.</p> <p>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.</p>
System Components		
System	CT Exprès Injector Unit CT Exprès Control Panel	CT Exprès III Injector Unit CT Exprès III Control Panel
Accessories	CT Exprès Hand Switch CT Exprès Bottle Insulator CT Exprès Stand	CT Exprès III Hand Switch CT Exprès III Bottle Insulator CT Exprès III Pedestal Pole and Wheel Base CT Exprès III Printer (Optional)
Disposables	CT Exprès Day Set III <i>HP</i> CT Exprès Patient Set CT Exprès Bottle Spike Type B (25mm)	CT Exprès Day Set III CT Exprès Patient Set CT Exprès Bottle Spike Type A (30mm) CT Exprès Bottle Spike Type B (25mm)
Physical Design		
Weight	Injector: Approx. 10 kg Console: Approx. 2.1 kg	Injector: Approx. 10kg Console: Approx. 1.7kg
Dimensions	Injector: 44 x 32 x 16 cm Console: 30 x 20 x 22 cm	Injector: 44 x 32 x 16 cm Console: 30 x 20 x 20 cm
Power Requirement: Rated voltage: Rated current: Rated frequency:	110 to 120 V AC 1.6 A 60Hz	110 to 120 V ac 1.6 A 60 Hz
Display: Type: Resolution: Technology:	Colour LCD with touch screen 800 x 600 pixel TFT (Thin Film Transistor)	VFD display with hard button technology
Characteristic		
Remote operation	Yes	Yes
Single patient use disposable	Patient Set	Patient Set
Designed to prevent reuse of disposables	Yes	Yes
Operational Characteristics		
Injection capabilities	Up to 24 phases per patient (8 phases per injection;	Up to 15 phases (5 phases per injection; up to 3

Contrast Media Delivery System	Subject Device	Predicate
	CT Exprès™ 3D	CT Exprès™ III™
	up to 3 injections per patient)	injections per patient)
Injection rates for contrast media	0.5 – 9.0 mL/s	0.5 – 9.9 mL/s
Injection rates for saline	0.1 – 9.0mL/s	0.5 – 9.9 mL/s
Injection Volume per injection	10 – 200mL per injection	0 – 200 mL
Flow rate and Volume accuracy	± 10% for a programmed injection volume between 10mL and 59mL ± 6% for a programmed injection volume between 60mL and 200mL	± 6%
Contrast media container volume	200 & 500mL	50 – 500 mL
Saline flush	Yes	Yes
Needle Size	16-24G	16-27 G
Injection pause	0 - 400 sec	0-99 sec
Scan delay	0 - 400 sec	0-99 sec
Injection protocol storage	unrestricted	100 protocols
Priming rate	1.5mL/s (manual) 6.0mL/s (automatic)	1 mL/s
Air Detection Principle	Ultrasound	Ultrasound
Technical Detection limit	0.04mL	0.04mL
Air Detector Alarm Limit	For programmed injection volume ≤ 35mL CM, 1.25mL For programmed injection volume >35mL CM, 1.25mL if fragment air bubble, otherwise an additional air volume of 0.75mL is tolerated. Note: The volume of the Patient Set (after the air detector) is 8mL	0.3 mL
Occlusion Detection Principle	Fail safe piezo-resistive pressure sensor	Fail-safe piezo-resistive pressure sensor
Occlusion Detection Alarm Limit	132 PSI ± 17.4 PSA (9.1 bar ± 1.2 bar)	8 bar ± 1 bar

Table 2. Side-by-Side Comparison Table, Disposables

Disposable	Subject Device	Predicate
Contrast Media Delivery System	CT Exprès™ 3D	CT Exprès™ III™
Manufacturer	Bracco Injengineering S.A.	Swiss Medical Care
Regulatory Status	K151048	K062265
Patient Set	Patient Set	Patient Set
Components	Patient Set Cassette Patient Set Tubing Pinch Clamp Patient connector with safety cap	Patient Set Cassette Patient Set Tubing Pinch Clamp Patient connector with safety cap
Colour of Pinch Clamp	Blue	White
Safety Feature against re-use	Break away pin designed to break on insertion	Break away pin designed to break on insertion
Day Set	Day Set III HP	Day Set III
Components	T-connector Contrast media line x2 Spike for saline line Saline line Filter x2 Reservoir x2 Tubing guide x2	T-connector Contrast media line x2 Spike for saline line Saline Line Filter x2 Reservoir x2 Tubing guide x2

Disposable	Subject Device	Predicate
Contrast Media Delivery System	CT Exprès™ 3D	CT Exprès™ III™
Tubing inner diameter	4 ± 0.07mm	3 ± 0.05mm
Tubing outer diameter	6 ± 0.07mm	4.1 ± 0.05mm
Contrast media line tubing material	PVC tubing	PVC tubing
Saline line tubing material	PVC tubing	PVC tubing
Bottle Spike	Bottle Spike Type B	Bottle Spike Type B
Size	25mm	25mm
Safety Feature against re-use	Spike tip designed to break off into bottle on removal	Spike tip designed to break off into bottle on removal