K071378

EmpowerCT/EmpowerCTA Injector System Special 510(k) Summary

JUN 13 2007

Contact Information:

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Trade Name: EmpowerCT and EmpowerCTA Injector Systems

Common Name: Radiographic CT Injector for Contrast Medium, Automatic

Classification:
System, X-Ray, Tomography, Computed
Plethysmograph, Impedance
Cardiovascular/Radiology/Injector, Contrast medium, Automatic
21 CFR 892.1750 (Product Code JAK)
21 CFR 870.2770 (Product Code DSB)
21 CFR 870.1650 (Product Code IZQ)

Currently Marketed Devices:
EmpowerCTA Injector System (K031571) (K063029)
EmpowerCT Injector System (K011160) (K063029)

New Indications for Use: The EmpowerCTA Injector system is intended for the vascular administration of contrast and flushing media and the EmpowerCT Injector system is intended for vascular administration of contrast. Both injector systems are used in conjunction with computed tomography (CT) scanning of the body with an optional interface to a CT scanner and an optional calculator for glomerular filtration rate (GFR).

Description of Modification:

The EmpowerCT and EmpowerCTA Injector Systems have been modified for a software change only specific to the Empower Remote Control. They have been modified to add an optional calculator for glomerular filtration rate (GFR). This optional calculator is used as an additional screening tool for the use of a CT contrast injection in conjunction with a CT scan. This calculator does not affect the safety or efficacy of the device. Nor does it affect the indications for use of the system.

Accessories:

There is no change to the accessories available with the CT or CTA Injector Systems.

- The EmpowerCT is currently available with or without the E-Z-EM EDA Device (K961845, K974621). The EmpowerCT Injector System is designed specifically for use with the following currently approved dedicated E-Z-EM disposables:

    - Fast*Load CT Syringe (K933846)
    - EDA Electrode Patch (K961845, K974621)
    - Empower Transfer Set (K041178)

- The EmpowerCTA Injector System is also currently available with or without the E-Z-EM EDA device (K961845, K974621) The EmpowerCTA Injector System is designed specifically for use with the currently approved dedicated E-Z-EM disposables:

    - Fast*Load CT Syringe (K933846)
    - CTA Dual Pack (K933846 and K031571)
    - EDA Electrode Patch (K961845, K974621)
    - Empower Transfer Set (K041178)
    - EmpowerCTA Connecting Tube (K031571)

Comparative Summary:

A comparison between the proposed E-Z-EM EmpowerCTA and EmpowerCT Injector Systems against the currently marketed Injector System devices are presented in the following tables.

Performance (Injector)	**Proposed Devices E-Z-EM EmpowerCT and EmpowerCTA Injector with optional GFR Calculator**	**Currently marketed devices E-Z-EM EmpowerCT (K011160)(K063029) and EmpowerCTA Injector (K031571)(K063029)**
Design	Syringe type injector, software controlled, venous side, low pressure injector.	Same as Proposed
Anatomical Sites	Inject contrast and flushing media into a peripheral vein	Same as Proposed
Flow Rate	0.1 to 10 mL/sec in user specified increments of 0.1 mL/sec Accuracy: ±5% of programmed rate +0.1 mL/sec	Same as Proposed
Delivery Volume	1 to 200 mL in user specified increments of 1 mL Accuracy: ±2% of programmed volume +1ml)	Same as Proposed
Maximum Pressure	40 to 300 psi in user specified increments of 1 psi Accuracy: ±10% of programmed pressure limit + 10 psi	Same as proposed
Pressure Limiting	Yes	Same as Proposed
Operating Principle	Electric Motor Linear Actuated Syringe Piston	Same as Proposed
Power Supply	Medical Grade Switching Power Supply	Same as Proposed
Remote Start Switch	Yes	Same as Proposed
Air Detection	User Observed	Same as Proposed
Display	Color Touch screen	Same as Proposed
Maximum Number of Injection Phases per Protocol	8 Contrast and Saline (CTA) 8 Contrast (CT)	Same as Proposed
Maximum Number of Stored Injection Protocols	50	Same as Proposed
Programmed Pause	Yes	Same as Proposed
Connectivity	Yes either via a CT Trigger port or via a data communication method.	Same as Proposed
Special Feature	Optional GFR Calculator	No
Target Population	Humans	Same as Proposed

DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Mr. Steven Hartman
Director Engineering
E-Z-EM, Inc.
750 Summa Avenue
WESTBURY NY 11590

JUN 13 2007

Re: K071378
Trade/Device Name: E-Z-EM EmpowerCT/CTA Injector System with Optional EDA
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulation Number: 21 CFR 870.2770
Regulation Name: Impedance plethysmograph
Regulation Number: 21 CFR 870.1650
Regulation Name: Angiographic injector and syringe
Regulatory Class: II
Product Code: JAK, DSB, and IZQ
Dated: May 15, 2007
Received: May 17, 2007

Dear Mr. Hartman:

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

INDICATIONS FOR USE

510(K) Number: K071378

510(k) Application: Special 510(k) Device Modification

Device Name: E-Z-EM EmpowerCT/CTA Injector System with optional EDA

Indications for Use:

Injector: Administration of contrast and flushing media in conjunction with computed tomography (CT) scanning of the body with an optional interface to a CT scanner

EDA: The Extravasation Detection Accessory is indicated for the detection of extravasations of contrast media during CT using a power injector.

Prescription Use ✓ **(Yes)**
(Per 21 CFR 801.109)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **OR** **Over-the-Counter Use**
(Per 21 CFR 801.109)

(Division Sign-Off)
Division of Reproductive, Abdominal,
and Radiological Devices
510(k) Number K071378