

K063029

EmpowerCT/EmpowerCTA Injector System Special 510(k) Summary

Contact Information:

Tracey Campbell
E-Z-EM, Inc.
Director of Regulatory Affairs
1111 Marcus Avenue, suite LL-26
Lake Success, NY 11042
Phone: 516-333-8230, ext. 3407
Fax: 516-302-2911

NOV - 2 2006

Steven Hartman
E-Z-EM, Inc.
Director of Engineering
750 Summa Avenue
Westbury, NY 11590
Phone: 516-333-8230, ext. 2345
Fax: 516-333-2334

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:**

E-Z-EM EmpowerCTA Injector System (K031571)
EmpowerCT Injector System (K011160)

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.

**Description of
Modification:**

The EmpowerCT and EmpowerCTA Injector Systems have been modified to allow for connection to a CT scanner. This connection will allow data and state information to be synchronized between the scanner and injector systems. The EmpowerCT and EmpowerCTA Injector Systems are currently marketed as injection systems that use one or two consumable syringe(s) to displace contrast media and

flushing media (EmpowerCTA only) to the patient. A motor driven linear actuator mechanism controls displacement of the syringe piston.

The currently marketed injector systems consist of four components. These include the Injector, Remote Control, EDA and Power Supply.

Consistent with currently marketed devices, the proposed device will allow the user to administer the contrast media to the patient by specifying the following variables at the remote control.

- Volume-** Volume is selectable from 1 ml to 200 ml in 1 ml increments.
- Flow Rate-** Flow rates are selectable from 0.1 to 10 ml/sec in increments of 0.1ml/sec.
- Pressure-** Maximum syringe pressure is selectable from 40-300 psi in increments of 1 psi

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)
 - EDA Electrode Patch (K961845, K974621)
 - Empower Transfer Set (K041178)
 - EmpowerCTA Connecting Tube (K031571)

Comparative Summary:

In the proposed device modification, the EmpowerCT and EmpowerCTA Injectors in addition to having a CT Trigger option, will now have a mechanism to synchronize data and state information communication between the CT Injector System and the CT Scanner. The connectivity is the only modification being made to the EmpowerCT and EmpowerCTA Injector Systems.

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 scanner interconnect	Currently marketed devices E-Z-EM EmpowerCT (K011160) and EmpowerCTA Injector (K031571)
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 A Accuracy: $\pm 5\%$ of programmed rate +0.1 mL/sec	Same as Proposed
Delivery Volume	1 to 200 mL in user specified increments of 1 mL Accuracy: $\pm 2\%$ of programmed volume +1ml)	Same as Proposed
Maximum Pressure	40 to 300 psi in user specified increments of 1 psi Accuracy: $\pm 10\%$ of programmed pressure limit + 10 psi	Same as proposed
Pressure Limiting	Yes	Yes
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	Yes
Air Detection	User Observed	Same as Proposed
Display	Color Touch screen	Same as Proposed
Maximum Number of Injection Phases per Protocol	8 (Contrast Only) or 2 (1 Contrast followed by 1 Saline) or 3 (2 Contrast followed by 1 Saline)	Same as Proposed
Maximum Number of Stored Injection Protocols	50	Same as Proposed
Programmed Pause	Yes	Yes
Connectivity	Yes either via a CT Trigger port or via a data communication method. <u>The data communication method was developed in accordance with the CAN-CiA specification DSP 425.</u>	Yes via a CT Trigger port only.
Target Population	Humans	Same as Proposed



DEPARTMENT OF HEALTH & HUMAN SERVICES

Food and Drug Administration
9200 Corporate Blvd.
Rockville MD 20850

Ms. Tracey Campbell
Director, Regulatory Affairs
E-Z-EM, Inc.
750 Summa Avenue
WESTBURY NY 11590

NOV - 2 2006

Re: K063029
Trade/Device Name: E-Z-EM Empower CT/CTA Injector System with optional EDA
Regulation Number: 21 CFR §892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Codes: JAK, DSB and IZQ
Dated: September 29, 2006
Received: October 2, 2006

Dear Ms. Campbell:

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.



Protecting and Promoting Public Health

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.

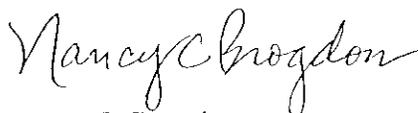
This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to 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
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

INDICATIONS FOR USE

Number: K063029
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.

Concurrence of CDRH, Office of Device Evaluation (ODE)

Christine A. Seymour
(Division Sign-Off)
Division of Reproductive, Abdominal, and
Radiological Devices
510(k) Number K063029

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