DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JUN 19 2003

Mr. Steven Hartman
Senior Project Engineer, CT Products
E-Z-EM, Inc.
717 Main Street
WESTBURY NY 11590

Re: K031571
Trade/Device Name: E-Z-EM EmpowerCTA Injector System with Optional EDA
Regulation Number: 21 CFR 870.1650
Regulation Name: Automatic contrast medium injector
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: 74 IZQ and 90 JAK
Dated: May 19, 2003
Received: May 22, 2003

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 (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); 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 the letter:

8xx.1xxx	(301) 594-4591
876.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4616
884.2xxx, 3xxx, 4xxx, 5xxx, 6xxx	(301) 594-4616
892.2xxx, 3xxx, 4xxx, 5xxx	(301) 594-4654
Other	(301) 594-4692

Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. 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 may be obtained 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,

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) Application: Special 510(k) Device Modification

Device Name: E-Z-EM EmpowerCTA Injector System with optional EDA

Indications for Use:

CT Injector: Administration of contrast and flushing media in conjunction with computed tomography (CT) scanning of the body.

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)

David A. Lynn

(Division Sign-Off)
Division of **Reproductive, Abdominal,** and Radiological **Devices**
510(k) Number K073571

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

JUN 19 2003

K031571

Visualize a healthier world

EmpowerCTA Injector System 510(k) Summary

Submitter's Information:	E-Z-EM, Inc. 717 Main Street Westbury, NY 11590
Telephone Number:	(516) 333-8230, ext. 2345
Fax Number:	(516) 333-8278
Contact:	Steven Hartman, Senior Project Engineer, CT Injectors
Date Prepared:	May 19, 2003
Trade Name:	EmpowerCTA Injector System (Trademark Pending)
Common Name:	CT Injector
Classification Name:	Injector, Syringe, Extra-Luminal Plethysmograph, Impedance
Predicate Device:	EmpowerCT Injector System, K011160 (Internal Project Name, and Name Used in the 510(k) Application: E-Z-EM PercuPump 2001 CT Injector)

Indications for Use:

CT Injector: Administration of nonionic and ionic compounds and flushing media in conjunction with computed tomography (CT) scanning of the body.

The EDA is intended to detect extravasations of ionic and non-ionic contrast media during powered CT contrast injections.

Device Description:

The EmpowerCTA Injector System is an injection system that uses one or two consumable syringe(s) to displace contrast media and flushing media to the patient. A motor driven linear actuator mechanism controls displacement of the syringe piston. This method of contrast injection is consistent with predicate devices from E-Z-EM for over 12 years. This new version of the EmpowerCT Injector family primarily addresses the addition of a second syringe for the device for purposes of displacing flushing media.

A summary of the device as compared to the predicate device is as follows:

Comparative Summary Tables

	Proposed Device	Predicate Device
	EmpowerCTA Injector	**EmpowerCT Injector (PercuPump 2001)**
Indication for Use	Administration of nonionic and ionic compounds and flushing media in conjunction with computed tomography (CT) scanning of the body	Administration of nonionic and ionic compounds in conjunction with computed tomography (CT) scanning of the body
Design	Syringe type injector, software controlled, venous side, low pressure injector.	Same
Anatomical Sites	Inject contrast and flushing media into a peripheral vein	Inject contrast media into a peripheral vein
Radiation	No ionizing radiation emitted	Same
Thermal	No thermal energy introduced into patient	Same

	Proposed Device	Predicate Device
	EmpowerCTA Injector	**EmpowerCT Injector (Percupump 2001)**
Injector Head	Located Adjacent to CT Scanner Gantry via Floor or Overhead Mounting	Same
Power Supply	Switching Power Supply in Dedicated Enclosure	Switching Power Supply in Dedicated Enclosure
Remote Control	Located Adjacent to CT Scanner Console via Table or Wall Mounting	Same
EDA (Extravasation Detection Accessory)	Located in Dedicated Enclosure mounted to same Floor or Overhead Mounting as Injector Head	Same
Pendant	Dedicated Single Button, Start/Pause connected to Injector Head and/or Remote	Same

	Proposed Device	Predicate Device
	EmpowerCTA Injector	**EmpowerCT Injector (Percupump 2001)**
Syringe	Existing 200 ml, Proprietary E-Z-EM Interface (Catalog No. 6720)	Same
EDA Electrode Patch	Existing Proprietary E-Z-EM Electrode Patch (Catalog No. 7881)	Same
EDA Patient Cable (Semi-Disposable)	Existing Patient Cable (Catalog No. 9871)	Same

Performance (Injector)	Proposed Device EmpowerCTA Injector	Predicate Device EmpowerCT Injector (Percupump 2001)
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	0.1 to 10 ml/sec in user specified increments of 0.1 ml/sec Accuracy: ±5% of programmed rate +0.1 ml/sec)
Delivery Volume	1 to 200 ml in user specified increments of 1 ml Accuracy: ±2% of programmed volume +1ml)	1 to 200 ml in user specified increments of 1 ml Accuracy: ±2% of programmed volume +1ml
Maximum Pressure	50 to 300 psi in user specified increments of 1 psi Accuracy: ±10% of programmed pressure limit + 10 psi)	20 to 300 psi in user specified increments of 1 psi Accuracy: ±10% of programmed pressure limit + 10 psi)
Pressure Limiting	Yes	Yes

Performance (EDA)	Proposed Device EmpowerCTA Injector	Predicate Device EmpowerCT Injector (Percupump 2001)
Bio-Impedance Sensing	Range: 10 to 250 Resolution: 1/3 Ohm Accuracy: +/-10% Endpoints calibrated to 10 Ohm +10% -0% and 250 Ohm -10% +0%	Same
Indicated Extravasation Detection Threshold	20 ml	Same

Environmental Requirements	Proposed Device EmpowerCTA Injector	Predicate Device EmpowerCT Injector (Percupump 2001)
Operating Temperature Operating Humidity, Operating Altitude & Storage Temperature	Meets Requirements set forth in IEC/EN60601-1, Medical Electrical Equipment Part 1: General Requirements for Safety	Same
Electromagnetic Compatibility (EMC)	Meets Requirements set forth in IEC/EN 60601-1-2, Medical Electrical Equipment Part 1: Collateral Standard, Electromagnetic Compatibility CISPR 11 (EN55011: 1998/1999) IEC 60601-1-2: 1993/2001 EN61000-4-2: 1995 EN61000-4-3: 1996 EN61000-4-4: 1995 EN61000-4-5: 1995 EN61000-4-6: 1996 EN61000-4-8: 1993 EN61000-4-11: 1994	Meets Requirements set forth in IEC/EN 60601-1-2, Medical Electrical Equipment Part 1: Collateral Standard, Electromagnetic Compatibility CISPR 11 IEC 801-2 IEC 801-3 IEC 801-4 IEC 801-5
UL/CSA	Medical Device Listing to UL 2601-1 / CSA C22.2 No. 601.1, Electrical Class II, Type B Isolation rating, Injector, Type CF, Isolation rating, EDA	Same
Energy Requirements	100/240 VAC 50/60 Hz Auto Seeking	Same
Shock and Vibration	International Safe Transit Authority (ISTA), Project 3C	Same

	Proposed Device	Predicate Device
Injector Head Displays and Controls	**EmpowerCTA Injector**	**EmpowerCT Injector (PercuPump 2001)**
Display	240 x 180 Pixel Electrolumenescent Display	Same
Syringe Advance Slow	Membrane Key	Same
Syringe Advance Fast	Membrane Key	Same
Syringe Retract Slow	Membrane Key	Same
Syringe Retract Fast	Membrane Key	Same
Auto Initialize	Membrane Key	Same
Replace Syringe	Membrane Key	Same
Test Injection	Membrane Key	Same
Auto-Fill	Membrane Key	Same
Begin Fill	Membrane Key	Same

	Proposed Device	Predicate Device
Injector Head Displays and Controls "Continued"	**EmpowerCTA Injector**	**EmpowerCT Injector (PercuPump 2001)**
Increase Flow Rate	Membrane Key	Membrane Key
Decrease Flow Rate	Membrane Key	Membrane Key
Hand Knob	Direct Connection to Drive Mechanism	Same
Syringe Warmer	Snap On	Same
Illuminated Stop/Arm/Run/Pause Status Indicator	LED	LED

Remote Control Display and Controls	Proposed Device EmpowerCTA Injector	Predicate Device EmpowerCT Injector (PercuPump 2001)
Display	800 x 600 Color TFT LCD with Touchscreen Overlay	800 x 600 Color TFT LCD with Touchscreen Overlay
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)	8
Maximum Number of Stored Injection Protocols	50	50
Programmed Pause	Yes	Yes
External CT Trigger Port	Yes	Yes
Audio Speaker	Yes	Yes

EDA Display and Controls	Proposed Device EmpowerCTA Injector	Predicate Device EmpowerCT Injector (PercuPump 2001)
Display	EDA Function Supported within Remote Control Display and Touchscreen Field	Same