APR - 3 1998

Oz Power Syringe
510 (k) Summary of Safety and Effectiveness

Device Information:
Trade Name: Oz Power Syringe
Common Name: Angiographic Injector and Syringe
Classification Name: DXT Injector and Syringe, Angiographic

Predicate Devices:
MedRad Mark V Angiographic Injector (Ref. 510 (k) # K822536)
Sherwood Medical Monoject 35cc Syringe (Ref. 510 (k) # K852640)

Device Description:
The Oz Power Syringe consists of a 35cc syringe that is manually powered by a lever arm which attaches to a base. As the lever arm is raised, the syringe is tilted with the distal tip pivoting on a pin while the plunger tilts to a higher angle. The mechanism is designed to stop the plunger as the lever arm is raised to pull the plunger back in the syringe barrel to 35cc. At this position, the lever arm is approximately at a 45 degree angle from the base and the syringe is tilted to help produce power as the lever arm will be pushed downward to deliver the contrast media in the syringe.

The operator loads the syringe by pulling back on the plunger to draw in the contrast, then pushes the plunger forward to remove air, as is done with a traditional manual syringe. To deliver contrast media, the operator presses down on the lever handle. The operator can easily adjust the delivery pressure in response to fluoroscope or x-ray imaging, or in response to patient comfort levels, by simply adjusting the manual force applied to the lever.
The Oz Power Syringe allows the operator to produce more pounds per square inch pressure than normal syringe use. By applying 60-70 pounds of downward pressure on the lever, the operator can easily achieve a 200-350 psi delivery pressure. It is easy to load and inject. It is easy to control and requires much less space than electrically driven power injector equipment.

This device enables the operator to produce sufficient pressures to achieve proper contrast delivery, while maintaining control throughout the delivery process. It is very important that the proper amount of contrast media, as well as the pressure and rate at which it is delivered, be controlled for safe and desirable results to both the operator and the patient.

Intended Use:
Injection of contrast media into the heart, great vessels, and coronary arteries, to study the heart and vessels by x-ray photography.

Comparison to Predicate Device:

	Oz Power Syringe (Subject Device)	MedRad Mark V Angiographic Injector 510(k) # K822536	Sherwood Medical Monoject 35cc Syringe 510(k) # K852640
Intended Use:	Injection of contrast media into the heart, great vessels, and coronary arteries, to study the heart and vessels by x-ray photography	Same	Same
Operating Principle:	Manual delivery through syringe with force applied to syringe plunger through lever action	Automated delivery through syringe using electronic screw drive delivery control	Manual delivery through syringe with force applied to syringe plunger by hand
Design Features:	• Clear plastic handle, base, and syringe • Manually controlled	• Metal body, clear plastic syringe • Automated screw	• Clear plastic syringe • Manually controlled • Lightweight design

	• Lightweight design • Female luer connection • Completely disposable	drive operation • Heavier, larger design • Female luer connection • Reusable equipment/ disposable syringe	• Female luer connection • Completely disposable
Materials:			
Syringe	Polypropylene	Polypropylene	Polypropylene
Plunger	Polypropylene	Polypropylene	Polypropylene
Plunger Tip	Rubber	Rubber	Rubber
Handle/Base	Clear ABS	N/A	N/A
Dimensions:			
Length	12"	24"	9"
Width	4"	4"	1"
Height:	4"	9"	1"
Weight:	13 oz.	40 lbs.	3 oz.
Volume:	1cc-35cc	65cc-260cc	1cc-35cc
Flow Rate:	Operator controlled	Machine controlled	Operator controlled
Injection Pressure:	1-600 psi (appx based on operator control)	150 - 1200 psi	1-450 psi (appx based on operator control)
Packaging:	Tyvek pouch	Form-fill tray w/ Tyvek lid	Form-fill tray w/ Tyvek lid
Labeling:	Sterile, non-pyrogenic prescription	Same	Same
Expiration Date:	1 year	3 years	3 years

Non-Clinical Testing:

The following tests were conducted to establish substantially equivalent performance between the subject and predicate devices:

- Pressure through system directly into pressure gauge (closed)
- Pressure through system flowing through catheters (open)
- Pressure through present power injector system (open)
- Luer suction test
- High pressure leakage
- High pressure burst
- Luer test
- Break testing
- Packaging Integrity

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

APR - 3 1998

Dr. Azam Anwar
President
Cardiovascular Innovations
4331 Arcady
Dallas, TX 75205

Re: K973334
Trade Name: Oz Power Syringe
Regulatory Class: II
Product Code: DXT
Dated: August 22, 1997
Received: September 4, 1997

Dear Dr. Anwar:

We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent 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). 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 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any

obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 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 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4618. 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" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers 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,

Thomas J. Callahan

Thomas J. Callahan
Director
Division of Cardiovascular, Respiratory,
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

STATEMENT OF INTENDED USE FORM

510 (k) #: **K97334**

Device Name: **Oz Power Syringe**

Indications for Use:

Injection of contrast media into the heart, great vessels, and coronary arteries, to study the heart and vessels by x-ray photography

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K973334

Concurrence of CDRH, Office of Device Evaluations (ODE)

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