K984418

MAR 11 1999

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter's Name:	Medrad Inc.
Submitter's Address:	One Medrad Drive, Indianola, PA 15051 USA
Telephone Number:	(412) 767-2400, ext. 3536
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Contact Person:	Frank Pelc
Date:	December 9, 1998
Proprietary Name:	Universal Adjustable T-Rail Table Bracket
Common Name:	Table Bracket
Classification:	74 DXT
Classification Name:	Injector and Syringe, Angiographic
Predicate Device:	Medrad Universal T-rail Table Bracket, catalog number KMA-339

Medrad, Inc.
One Medrad Drive
Indianola, PA 15051-0780
(412) 767-2400

Substantial Equivalence - The Universal Adjustable T-Rail Table Bracket, catalog number KMA-350, is substantially equivalent to Medrad's Universal T-Rail Table Bracket, catalog number KMA-339, a pre-amendment device. Both products have the same intended use to support Medrad Mark IV, Mark V, and Mark V Plus Angiographic Injectors and other Medrad injectors of similar weight (22 lbs. for the Mark IV, 19 lbs. for the Mark V and Mark V Plus) and post size. Both fit on table rails from ¼ to ½ inches thick and 7/8 to 1-1/8 inches high. The primary differences are that the design of the proposed KMA-350 Table Bracket is modified to allow the bracket height to be adjusted; and that the KMA-350 Table Bracket can be secured to a table rail without needing to be disassembled.

A table comparing the characteristics of both table brackets is provided below.

Comparison Table

	Proposed Device: KMA-350 Universal Adjustable Table Bracket	**Predicate Device: KMA-339 Universal Table Bracket**
Intended Use	An accessory for supporting Medrad Mark IV, Mark V, and Mark V Plus Angiographic injectors and other Medrad injectors of similar weight and post size. (These Medrad angiographic injectors are intended to be used to deliver intravenous contrast medium into humans for angiographic diagnostic procedures.)	An accessory for supporting Medrad Angiographic Injectors.
Dimensions (Height)	12 to 17 inches	17-3/8 inches
Height Adjustable	Yes (5 inches)	No
Table Rail Size	From ¼ to ½ inches thick and 7/8 to 1-1/8 inches high	From 1/8 to ½ inches thick and 7/8 to 1-1/4 inches wide
Electrical Isolation	Yes (The bracket is isolated from the injector head via a plastic bushing at the injector head collar.)	Same

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Frank Pelc
Regulatory Affairs Coordinator
Medrad Inc.
One Medrad Drive
Indianola, PA 15051

Re: K984418
Trade Name: Universal Adjustable T-Rail Table Bracket
Regulatory Class: II
Product Code: DXT
Dated: February 18, 1999
Received: February 19, 1999

Dear Mr. Pelc:

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 (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). 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) 594-4586. 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 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, Ph.D.
Director
Division of Cardiovascular, Respiratory
And Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

INDICATION FOR USE

510(k) Number: K984418

Device Name: Universal Adjustable T-Rail Table Bracket

Indications for Use/Intended Use:

The Universal Adjustable T-Rail Table Bracket is intended to be used as an accessory for supporting Medrad Mark IV, Mark V, and Mark V Plus Angiographic injectors and other Medrad injectors of similar weight and post size.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

for TJC

(Division Sign-Off)
Division of Cardiovascular, Respiratory,
and Neurological Devices
510(k) Number K984418

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

(Optional Format 1-2-96)