K992225

SEP 7 1999

SUMMARY OF SAFETY AND EFFECTIVENESS
(As required by 21 CFR 807.92)

1. General Information

Classification:	Class II Magnetic Resonance Imaging (MRI) System
Common/Usual Name:	Magnetic Resonance Imaging (MRI) Option
Proprietary Name:	Quantitative Flow
Establishment Registration:	Picker International, Inc. World Headquarters 595 Miner Road Highland Heights, Ohio 44143 Contact: Elaine K. Keeler, Ph.D Phone: (440) 473-3000 FDA Owner Number: #1580240 FDA Registration Number: #1525965
Performance Standards:	No applicable performance standards have been issued under section 514 of the Food, Drug and Cosmetic Act.

2. Intended Uses

The intended use of Quantitative Flow is to non-invasively obtain and map quantitative flow and velocity measurements from a vessel during a cardiac cycle using the principles of NMR.

3. Device Description

Picker's Quantitative Flow functionality includes the ability to create reference magnitude, phase velocity, phase contrast, phase contrast velocity and reference magnitude velocity images. The operator can define up to eight regions of interest on the phase velocity images and perform several quantitative measurements. When combined with cardiac gating, the operator can observe changes in velocity and flow throughout the cardiac cycle.

4. Safety and Effectiveness

The Quantitative Flow functionality included in Picker's Application Suite for Cardiovascular Assessment is similar in technological characteristics and intended use to the GE Flow Analysis Option. The following table has been created to demonstrate their substantial equivalence.

Substantial Equivalence Chart

Parameter	Quantitative Flow	Predicate Device - GE Flow Analysis Option (K924605)
System Compatibility	1.5T Edge Eclipse and 1.0T Vista Polaris	1.5T Signa Advantage
Sequences	2D Phase Contrast, FAST	2D and 3D Phase Contrast, Cine Phase Contrast
Acquisition Options	ECG-triggered cardiac gating, PPG-triggered cardiac gating and phase encode grouping.	Flow compensation, respiratory compensation, ECG-triggered cardiac gating, peripheral-triggered cardiac gating, graphic prescription, spatial presaturation, no phase wrap, rectangular FOV.
Image Types Produced	Reference Magnitude Image, Phase Velocity, Phase Contrast, Phase Contrast Velocity, and Reference Magnitude Velocity.	Magnitude, Flow and Speed Images
Range of Velocities	5-600 cm/sec	Approx. 20-400 cm/sec
Accuracy of Flow Measurements	In vivo testing demonstrated that flow could be measured to within 3.9% ± 0.8 for constant flow and 3.5% ± 2.2 for pulsatile flow.	In vivo testing demonstrated that flow could be measured to within 5.26% ± 3.77 for constant flow and 5.73% ± 3.0 for pulsatile flow.
Parameter Requirements	Cine images for quantitative analysis can only be sensitized in one direction.	Images must be acquired in the CINE mode and the flow axis must represent through-plane flow. The slice thickness must be less than 20mm.
ROI Drawing	User can manually draw up to eight ROIs for flow measurements.	User can manually draw up to four ROIs for flow measurements.
Data Output	Outputs include: - avg. velocity vs. time graph - volume vs. time graph - histogram of pixel velocities - ROI statistics (mean, STD) - Qp/Qs ratio calculations - Regurgitate volumes	Outputs include: - avg. velocity graph - avg. flow graph - ROI statistics (mean, max, min) - Flow calculations (positive volume, negative volume, cardiac output, stroke volume)
Intended Use and Indications for Use	The intended use of Quantitative Flow is to non-invasively obtain and map quantitative flow and velocity measurements from a vessel during a cardiac cycle using the principles of NMR.	The Signa Advantage Flow Analysis Option charts flow and velocity changes during the cardiac cycle. This post processing technique provides flow information acquired non-invasively during the cardiac cycle.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 17 1999

Elaine K. Keeler, Ph.D.
Manager, Clinical Science
Picker International, Inc.
595 Miner Road
Highland Heights, OH 44143

Re: K992225
Quantitative Flow
Dated: July 2, 1999
Received: July 2, 1999
Product Code: 90 LNH
Regulatory Class: II (two)
21.CFR 892.1000

Dear Dr. Keeler:

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) 594-4613. 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,

CAPT Daniel G. Schultz, M.D.
Acting Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat,
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

510(k) Number (if known): K992225

Device Name: Quantitative Flow

Indications for Use:

The intended use of Quantitative Flow is to non-invasively obtain and map quantitative flow and velocity measurements from a vessel during a cardiac cycle using the principles of NMR.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Seguin

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992225

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

(Optional Format 1-2-96)