SEP 16 1999

EXHIBIT #1

510(K) SUMMARY

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K992892

1. Submitter's Identification:

Magnetic Moments, LLC
P.O. Box 721425
Berkley, MI 48072-0425

Date Summary Prepared: August 1999

Contact: Anil N. Shetty, Ph.D

2. Name of the Device:

Stepping Kinematic Imaging Platform (SKIP™)

3. Predicate Device Information:

a. Philips Gyroscan NT Platform with MobiTrak™ Package, K# 980645, Philips Medical Systems, NA, Shelton, CT

b. Siemens Magnetom Vision, K# 940541, Siemens, CA

c. General Electric Signa Horizon LX, K# 942604, General Electric Medical Systems

d. Picker Eclipse VISTA, K# 931544, Picker International, Inc.

4. Device Description:

The "SKIP™" table consists of three major components: two platforms consisting of a multitude of nonferromagnetic wheels, or rollers, which contain glass bearings and one overlying movable table. The matrix of all major components consist of plastic material. The axels of the wheels or rollers are also made of plastic material. Small minor components of the device include several straps attached to plastic connectors which are used to immobilize the patient on the moving table and, finally, a plastic mount for suspending the existing MRI imaging surface coil over the patient.

5. **Intended Use:**

The device is intended to translate (reposition) the patient manually within a magnetic resonance imaging machine, through the magnet bore, in order to center different regions-of-interest at the center of the magnetic field for either multistation MRA with single dose injection or multistation MRI, using existing system hardware, software and imaging coils.

6. **Comparison to Predicate Devices:**

The "SKIP™" device is substantially equivalent to previously cleared 510(k)'s with MRI tables, and, particularly, the Philips Gyroscan NT Platform with MobiTrak™ Package, K# 960973.

The MobiTrak™ Package accessory to the Gyroscan NT MR Scanner (Philips) is capable of rapid translation of patient to center different anatomical imaging site in to the center of the magnet. The repositioning of patient is performed without actually removing the patient as done in conventional scanners and is performed between measurements when no data is acquired. The MobiTrak™ Package allows rapid evaluation of the aorta and the lower extremity vasculature with a single dose of contrast. It incorporates standard existing contrast-enhanced MRA imaging software with the addition of table movement between two successive measurements to overcome the limitation of a single field-of-view in relation to the large field-of-view of interest. Currently, the package allows for moving existing patient table electronically.

Regarding our device, Stepping Kinematic Imaging Platform (SKIP™) has the same intended use as MobiTrak™. SKIP™ also allows for rapid repositioning of patient inside the magnet. The accessory device fits on any 1.5T MR scanner (GE, Picker, Siemens) and allows for rapid evaluation of the aorta and lower extremity vasculature with native contrast-enhanced MRA software. The present version incorporates the motion of a retrofitted table or platform, which is placed on the existing system-inherent MRI table. The SKIP™ is an accessory device that is non-ferromagnetic, requiring no additional electronic hardware or software for operation. The entire platform is moved back and forth manually instead of electronically.

7. **Discussion of Non-Clinical Tests Performed for Determination of Substantial Equivalence are as follows:**

Applicable questions outlined from the DRAED "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Device" were covered.

8. Discussion of Clinical Tests Performed:

Not Applicable

9. Conclusions:

The Stepping Kinematic Imaging Platform ("SKIP™") has the same intended use and similar technological characteristics as the predicate device's table claims. Moreover, biocompatibility testing, clinical literature and specification parameters demonstrate that any difference in their technological characteristics do not raise any new questions as to safety and effectiveness. Thus, the Stepping Kinematic Imaging Platform ("SKIP™") is substantially equivalent to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 16 1999

Ms. Susan D. Goldstein-Falk
Magnetic Moments,LLC
C/O mdi Consultants, Inc.
55 Northern Boulevard
Suite 200
Great Neck, NY 11021

Re: K992892
Stepping Kinematic Imaging Platform (SKIP™)
Dated: August 25, 1999
Received: August 27, 1999
Regulatory Class: II (TWO)
Product Code: 90 LNH
21 CFR 892.1000

Dear Ms. Goldstein-Falk:

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

Exhibit B

510(k) Number (if known): K992892

Device Name: Stepping Kinematic Imaging Platform (SKIP™)

Indications For Use:

The device is intended to translate (reposition) the patient manually within a magnetic resonance imaging machine, through the magnet bore, in order to center different regions-of-interest at the center of the magnetic field for either multistation MRA with single dose injection or multistation MRI, using existing system hardware, software and imaging coils.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ **(Per 21 CFR 801.109)** OR **Over-The-Counter Use** ____ **(Optional Format 1-2-96)**

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K992892