OCT 22 1998

CHAMCO INC.

American Made Medical Products

510(k) Summary

K982761

1. Submitter Information

1.1	Submitter:	CHAMCO, Inc. 798 Clearlake Road Cocoa, Fl 32922 Owner/operator number: 9034336
1.2	Contact:	David P Salvadorini PH: 407-774-4488 FX: 407-774-0599 email: dsalvadorini@compuserve.com
1.3	Date:	August 4, 1998

2.0 Device Name

2.1	Classification Panel:	Radiology
2.2	Classification Number:	892.100 Magnetic Resonance Diagnostic Device
2.3	Product Number:	90LNH
2.4	Product Nomenclature:	System, Nuclear Magnetic Resonance Imaging, Accessory
2.5	Device Classification:	II
2.6	Performance Standards:	None established under section 514 of the Food, Drug and Cosmetic Act
2.7	Trade Name:	Joint Motion Devices

2.7.2 Knee/Cervical Joint Motion Device	P/N 1026
2.7.3 Lumbar Joint Motion Device	P/N 1027
2.7.4 Wrist Joint Motion Device	P/N 1028
2.7.5 Ankle Joint Motion Device	P/N 1029
2.7.6 Shoulder Joint Motion Device	P/N 1030

2.7.7	Hip Joint Motion Device	P/N 1031
2.7.8	Joint Motion Device Package*	P/N 1032
2.7.9	Storage Cabinet	P/N 1033

*Includes all devices plus the storage cabinet

3.0 Predicate Device

3.1	K953918	Hitachi Medical Systems America, Inc.
3.2	Joint Motion Devices	Manufactured by CHAMCO, Inc.
3.3	Sept. 12, 1995	
3.4	Regulatory Class II	
3.5	21 CFR 892.1000/Procode: 90LNH	

3.6 These devices are identical to the predicate device. CHAMCO and Hitachi Medical Systems America, developed these devices together. CHAMCO has been the only manufacturer of these devices. CHAMCO intends to market these devices under its own name, and has adequate information demonstrating its legal right to distribute these devices.

4.0 Device Description

4.1 Function

The Joint Motion Devices provide constraint for the knee, cervical spine, ankle, wrist, lumbar spine, hip and shoulder anatomies to enable fixed position imaging, and kinematic (incremental stepped) motion of the knee, cervical spine, ankle, wrist, lumbar spine, hip and shoulder anatomies, and dynamic (continuous) motion of the knee, cervical spine, ankle, wrist , lumbar spine, hip and shoulder joint anatomies. Form, fit and function, as well as a determination that the devices do not adversely affect the magnetic field for imaging has been tested.

The Joint Motion Devices add clinical utility to all known open MRI diagnostic devices, including the Hitachi AIRIS™, Siemens Magnatom™, Toshiba OPART™, and Picker, Fonar, Phillips and GE Medical Systems Open MRI systems. In addition, several of the devices have use in higher tesla magnets where bore size is not a constraint.

4.2 Scientific Concepts

Identical to the predicate device

4.3 Physical and Performance Characteristics

Identical to the predicate device

5.0 Device Intended Use

Identical to the predicate device. The devices will enable the physician to evaluate the anatomy of the knee, cervical spine, ankle, wrist, lumbar spine, hip and shoulder anatomies, in a static mode as well as to evaluate the dynamic interaction of the different tissues (ligaments, cartilage, bone, muscle, fat). Such functional interaction may be useful in diagnosis.

6.0 Technological Characteristics

Identical to the predicate device. The devices are manually operated by the user. No active components (i.e. motors) are used and there are no ferromagnetic materials that could affect the scan field.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

OCT 22 1998

David P. Salvadorini
Director of Marketing
Chamco, Inc.
798 Clearlake Road
Cocoa, FL 32714

Re: K982761
Joint Motion Devices Package for MRI
Dated: August 4, 1998
Received: August 6, 1998
Regulatory class: II
21 CFR 892.1000/Procode: 90 LNH

Dear Mr. Salvadorini:

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 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,

Lillian Yin, Ph.D.
Director, Division of Reproductive,
Abdominal, Ear, Nose and Throat
and Radiological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Ver/3- 4/24/96

Indications for Use Statement

Applicant: CHAMCO, Inc.
798 Clearlake Road
Cocoa, Fl 32922
Owner/operator number: 9034336
David P Salvadorini
PH: 407-774-4488
FX: 407-774-0599
email: dsalvadorini@compuserve.com

510 (k) Number: K982761

Device Name: Joint Motion Device

Knee/Cervical Joint Motion Device	P/N 1026
Lumbar Joint Motion Device	P/N 1027
Wrist Joint Motion Device	P/N 1028
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Shoulder Joint Motion Device	P/N 1030
Hip Joint Motion Device	P/N 1031
Joint Motion Device Package*	P/N 1032
Storage Cabinet	P/N 1033

*Includes all devices plus the storage cabinet

Indications for Use:

The Joint Motion Devices are an accessory to MRI diagnostic devices, including the Hitachi AIRIS™, Siemens Magnatom™, Toshiba OPART™, Picker Outlook™, Fonar, and GE Medical Systems Open MRI systems. In addition, the devices may be used in any MRI system where the physical limits of the bore size is not a constraint.

The devices are built from plastics and nonferromagnetic materials, and hold patients securely during MRI imaging sequences. The devices also constrain joint motion to one of several user-designated planes of rotation, dependant upon the joint to be imaged, and emulate the natural motion of the joint.

The Joint Motion Devices increase the clinical utility of MRI systems to provide high quality, repeatable imaging and constraint for the knee, cervical spine, ankle, wrist, lumbar spine, hip and shoulder anatomies to enable fixed position imaging, and kinematic (incremental stepped) motion of the knee, cervical spine, ankle, wrist, lumbar spine, hip and shoulder anatomies, and

dynamic (continuous) motion of the knee, cervical spine, ankle, wrist , lumbar spine, hip and shoulder joint anatomies.

The devices will enable the physician to evaluate the anatomy of the knee, cervical spine, ankle, wrist, lumbar spine, hip and shoulder anatomies, in a static mode as well as to evaluate the dynamic interaction of the different tissues (ligaments, cartilage, bone, muscle, fat). Such functional interaction may be useful in diagnosis.

The intended patients are primarily drawn from a pool of those subjects undergoing diagnostic evaluation by physicians who are skilled in diagnosis and treatment of the disease process(es) under consideration.

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K982761

Concurrence of CDRH, Office of Device Evaluation, (ODE)

Prescription use X **OR** Over-the Counter _____

(Per 21 CFR 801.109)
(Optional Format 1-2-96)