510(k) SUMMARY

Choy Medical Technologies, Inc.
Choy Compression Frame

Submitter's Name, Address, Telephone Number, Contact Person and Date Prepared

Choy Medical Technologies
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Date Prepared: April 5, 2007

Regulatory Counsel

Jonathan S. Kahan. Esq.
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Washington, D.C. 20004

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Name of Device and Name/Address of Sponsor

Choy Compression Frame

Common or Usual Name

Axial compression frame

Classification Name

Accessory to Magnetic Resonance Imaging

K070965
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Predicate Devices

DynaMed AB's DynaWell axial compression frame (K992120)

Intended Use / Indications for Use

The Choy Compression Frame is indicated as an accessory for axial compression of the lumbar spine in CT and MR diagnostic imaging.

Technological Characteristics

The Choy Compression Frame consists of a fabric shoulder harness with straps and an MRI-compatible aluminum frame assembly with pneumatic pump. The pneumatic pump operates to apply a force to the patient and thus raise the patient's intradiscal pressure.

Performance Data

Clinical testing demonstrated the effectiveness of the Choy Compression Frame in increasing the sensitivity of MR diagnoses in matching presenting symptoms with MR findings without resulting in MRI image distortion from the device material.

Substantial Equivalence

The Choy Compression Frame is as safe and effective as the DynaWell compression device. The Choy Compression Frame has the same intended use and similar indications, technological characteristics, and principles of operation as its predicate device. Minor technological differences between the device and its predicate raise no new issues of safety or effectiveness. Performance testing demonstrates the effectiveness of the device in increasing the sensitivity of MR diagnoses without producing distortion in the MRI images. Thus, the Choy Compression Frame is as safe and effective as the predicate and thus, substantially equivalent.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 1 5 2007

Choy Medical Technologies, Inc.
% Mr. Jonathan S. Kahan
Official Correspondent
Hogan & Hartson LLP
Columbia Square
555 Thirteenth Street, NW
WASHINGTON DC 20004

Re: K070968
Trade/Device Name: Choy Compression Frame
Regulation Number: 21 CFR 892.1000
Regulation Name: Magnetic resonance diagnostic device
Regulatory Class: II
Product Code: LNH
Dated: October 18, 2007
Received: October 18, 2007

Dear Mr. Kahan:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and 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) that do not require approval of a premarket approval application (PMA). 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 (PMA), 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 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 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), please contact the Center for Devices and Radiological Health's (CDRH's) Office of Compliance at one of the following numbers, based on the regulation number at the top of this letter.

21 CFR 876.xxxx	(Gastroenterology/Renal/Urology)	240-276-0115
21 CFR 884.xxxx	(Obstetrics/Gynecology)	240-276-0115
21 CFR 892.xxxx	(Radiology)	240-276-0120
Other		240-276-0100

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding postmarket surveillance, please contact CDRH's Office of Surveillance and Biometric's (OSB's) Division of Postmarket Surveillance at 240-276-3474. For questions regarding the reporting of device adverse events (Medical Device Reporting (MDR)), please contact the Division of Surveillance Systems at 240-276-3464. You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Nancy C Brogdon

Nancy C. Brogdon
Director, Division of Reproductive,
Abdominal, and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

Indications for Use Statement

510(k) Number (if known): K070968

Device Name: Choy Compression Frame

Indications for Use:

The Choy Compression Frame is indicated as an accessory for axial compression of the lumbar spine in CT and MR diagnostic imaging.

Prescription Use __X___ AND/OR Over-The-Counter Use____
(Part 21 C.F.R. 801 Subpart D) (21 C.F.R. 807 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

(Division Sign-Off)
Division of Reproductive, Abdominal and Radiological Devices
510(k) Number K070968

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