AUG 13 1999

K992120

10 510(k) Summary

Product Trade name: **DynaWell**

Common name: Medical Compression Device, MCD

Classification name: Assessory for CT and MR equipment

Company & Specification developer: **DynaMed AB ,**

(Organizational Number 556 560-5515)

President S Mikulowski

Nybrokajen 7

102 41 Stockholm

Sweden

Prepared by,
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No equivalence claimed

10.1 Description of the device

Through compression of the spine with a Harness, two cords and a foot part improve CT and MR diagnostic of the spinal canal.

10.2 Statement of intended use

Criteria for when to use DynaWell:

Ideally, the examination is performed directly after the basic unloaded investigation and thus decided by the radiologist. The examination might be performed later and planned through the treating doctor or the radiologist.

DynaWell inclusion criteria

Patient from 15 to 65 years of age

Neurogenic claudition in all cases

Sciatica

- D-CSA (dural cross section area of the spinal canal in disc level) is below 130 mm^2
- Suspected dural sac deformation
- Disc herniation
- ~~Recess stenosis~~
- Foraminal stenosis
- Intraspinal synovial cyst
- Etc

DynaWell exclusion criteria

- Myofascia syndrome
- Vertebral trauma
- Tumor –malignancy
- Known or suspected osteoporosis
- Cardiopulmonary disease
- Trauma/Abuse
- Psychiatric history
- Language illiterate individual

The competence of the examination physician in judging what the proper inclusion or exclusion criteria's are is of outmost importance for the proper use of DynaWell

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

AUG 13 1999

Nils Ekeroth
C/O DynaMed AB
Nybrokajen 7
102 41 Stockholm
SWEDEN

Re: K992120
DynaWell
Dated: June 18, 1999
Received: June 23, 1999
Regulatory Class: II
21 CFR 892.1000/Procode: 90 LNH
21 CFR 892.1750/Procode: 90 JAK

Dear Mr. Ekeroth:

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

August 11:th, 1999

510(k) Number (if known): K992120

Device Name: DynaWell

Indication For Use: Accessory for axial compression of the Lumbar spine in CT and MR diagnostic imaging for enhanced and more relevant diagnosis during research and clinical purposes.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

David A. Bigger

(Division Sign-Off)
Division of Reproductive, Abdominal, ENT,
and Radiological Devices
510(k) Number K992120

Presciption Use ✓ OR Over-the-Counter Use_____
(Per 21 CFR 801.109)

(Optional format 1-2-96)