K072684 1 of 2

Section XII: 510(k) Summary of Safety and Effectiveness

SAFE MEDICAL DEVICES ACT OF 1990

510(k) Summary

NAME OF FIRM:
Mondeal Medical Systems GmbH
Moltkestr. 39
Tuttlingen, 78532
Germany

JAN - 4 2008

510(k) FIRM CONTACT:
Jay Evans
President
Mondeal North America, Inc.
P.O. Box 500521
San Diego, CA 92150-0521

TRADE NAME: Mondeal Endoscopic Recession and Release System

COMMON NAME: Endoscope And/Or Accessories

CLASSIFICATION: Manual Surgical Instrument for General Use (see 21 CFR, Sec. 878.4800)

Endoscope And/Or Accessories (see 21 CFR, Sec. 876.1500)

DEVICE PRODUCT CODE: OCZ, EMF
SUBSEQUENT PRODUCT CODE: KOG

SUBSTANTIALLY EQUIVALENT DEVICES
Instratek EndoTrack System **(K925083)**
Instratek Endoscopic Carpal Tunnel Instrument **(K922391)**
A.M. Surgical Mountable Endoscopic Knife **(K982142)**

DEVICE DESCRIPTION:

The **Mondeal Endoscopic Tissue Recession and Release System** is a minimally invasive device for gaining exposure to perform Gastrocnemius Tenotomy, Plantar Fasciitis Recession, and Carpal Tunnel Release.

The system is comprised of the instruments required to perform the above mentioned maladies in conjunction with commercially available endoscopes. The instruments include an obturator, cannula, cannula locking mechanism, elevator, rasp, suction handle, and knife(s).

The system requires bi-portal incisions to pass the cannula from one side of the intended recession/resection to the other, allowing the knife to perform a complete and verified recession/release.

The cannula locking mechanism aids the surgeon in ensuring the cannula does not move while performing the procedure.

The knife is offered in two different designs. One design is for forward cutting (away from the surgeon), the other is for reverse cutting (towards the surgeon). The benefits of each design are dependent upon which procedure the device is used for and surgeon preference.

INTENDED USE:

***Intended use*:**

The ***intended use*** of the **Mondeal Endoscopic Tissue Recession and Release System** is to endoscopically recess the gastrocnemius tendon or the plantar fascia ligament and to release the transverse carpal tunnel ligament.

Indications for use

The Mondeal Endoscopic Tissue Release Recession and Release System is indicated for the following:

Endoscopic Gastrocnemius Tenotomy (EGT) – as a tool for tissue recession in patients with heel cord contracture (equinus) who fail to respond to a full course of non-surigcal treatment.

Endoscopic Plantar Fasciotomy (EPF) – as a tool for tissue recession in patients with plantar fasciitis who fail to respond to a full course of non-surgical treatment.

Carpal Tunnel Release (ECTR) – as a tool for tissue release in patients who fail to respond to non-surgical treatment of carpal tunnel syndrome.

BASIS OF SUBSTANTIAL EQUIVALENCE

The Mondeal Endoscopic Tissue Recession and Release System is substantially equivalent to the Instratek and A.M. Surgical Endoscopic Tissue Recession and Release systems.

SUMMARY OF SAFETY AND EFFECTIVENESS:

The Mondeal Endoscopic Tissue Recession and Release System is shown to be safe and effective for the indications described in this submission.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

JAN - 4 2008

Mondeal North America, Inc.
% Mr. Jay Evans
P.O. Box 500521
San Diego, California 92150

Re: K072684
Trade/Device Name: Mondeal Endoscopic Tissue Recession and Release System
Regulation Number: 21 CFR 876.1500
Regulation Name: Endoscope and accessories
Regulatory Class: II
Product Code: OCZ
Dated: September 18, 2007
Received: September 21, 2007

Dear Mr. Evans:

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 (240) 276-0115. 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,

Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

MONDEAL
NORTH AMERICA INC.

Indications for Use

510(k) NUMBER: K072684

DEVICE NAME: **Mondeal Endoscopic Tissue Recession and Release System**

INDICATIONS FOR USE:

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Carpal Tunnel Release (ECTR) – as a tool for tissue release in patients who fail to respond to non-surgical treatment of carpal tunnel syndrome.

Prescription Use X AND/OR Over-The-Counter-Use _____

(Per 21 CFR 801 Subpart D) (21 CFR 801 Subpart C)

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

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K072684

Concurrence of CDRH, Office of Device Evaluation (ODE)