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510(k) Summary
Hall® Smart Guard® Irrigator
February 28, 2007

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D. Predicate/Legally Marketed Devices

The Hall® Smart Guard® Irrigator is a modification to:

1. Device name: Universal Drive System
2. Company name: Linvatec Corporation
3. 510(k) #: K971059

This 510(k) also includes the modified devices cleared in Special 510(k) #s:

- K060198, MicroPower Handpiece Medium Speed Drill
- K060260, MicroPower Handpiece High Speed Drill; and
- K060270, MicroPower Handpiece Oral Max High Speed Drill.

E. Device Description

The descriptions of the handpiece proposed in this special 510(k) and the *Universal Drive System and MicroPower Handpieces* are identical. The only differences between the legally marketed handpieces and the proposed device are the design of the fluid irrigation accessory/attachment and the sterile packaging. The existing irrigation accessories consist of plastic, snap-on clips that are attached to the bur guard on the distal tip of the handpiece. A stainless steel, single-lumen tube affixed to the clip can be attached to irrigation tubing to direct fluid to the surgical site. Irrigation inflow is controlled by a pump integral to the console. These attachments are available as both sterile, single use devices and as non-sterile, re-useable devices. The sterile irrigator is packaged in a double poly/poly pouch.

The proposed Hall® Smart Guard® Irrigator is also an accessory/attachment to a powered instrument system that provides irrigation at the surgical site. It is an injection-molded, polypropylene sleeve that fits over the bur guard on the distal tip of the handpiece. A stainless steel, single-lumen tube is insert-molded into the sleeve and can be attached to irrigation tubing to direct fluid to the surgical site. Irrigation inflow is controlled by a pump integral to the console. The proposed attachments will be available as sterile, single use devices. The Hall® Smart Guard® Irrigator will be packaged in a Tyvek®/poly pouch.

The polypropylene contains a thermochromatic dye that changes color when the internal temperature of the bur guard reaches 135° F and before the external temperature of the Hall® Smart Guard®Irrigator reaches 122°. This feature provides a heat indicator that serves two purposes:

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1. The temperature of the bur guard increases when the bearings are worn. It will alert the user that the bur guard should be serviced.
2. It will alert the user that the temperature of the Hall® Smart Guard® Irrigator has increased to the point that could result in potential patient injury.

In addition, the Hall® Smart Guard® Irrigator provides thermal insulation to the patient from heat that may be generated by the bur guard. The sleeve provides insulation to the patient by virtue of the physical barrier between the bur guard and the patient.

F. Intended Use

The Hall® Smart Guard® Irrigator is an accessory to a powered instrument system consisting of drills, saws and associated handpieces to perform the cutting of soft tissue and bone. The fields of application include: orthopedic, arthroscopic, neurosurgical, otolaryngological, plastic/reconstructive and oral/maxillofacial procedures.

G. Substantial Equivalence

The Hall® Smart Guard® Irrigator is substantially equivalent in scientific technology, design and intended use to the Universal Drive System and the MicroPower handpieces. The Universal Drive System was cleared by FDA under 501(k) K971059. Modifications to the Universal Drive System were cleared under special 510(k) numbers K060198, MicroPower Handpiece Medium Speed Drill; K060260, MicroPower Handpiece High Speed Drill; and K060270, MicroPower Handpiece Oral Max High Speed Drill. The changes made to the legally marketed devices have been tested to assure that the proposed modifications do not raise any new issues of safety and efficacy.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

ConMed Linvatec
% Ms. Elizabeth Paul
Manager, Regulatory Affairs
11311 Concept Boulevard
Largo, Florida 33773-4908

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Re: K070233
Trade/Device Name: Hall® Smart Guard® Irrigator
Regulation Number: 21 CFR 888.1100
Regulation Name: Arthroscope
Regulatory Class: II
Product Code: HRX
Dated: March 9, 2007
Received: March 12, 2007

Dear Ms. Paul:

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.

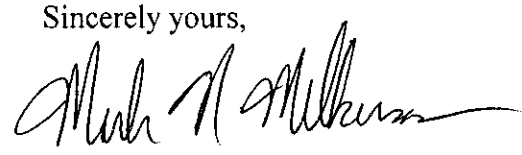
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish 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 Office of Compliance at (240) 276-0115. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). 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

Indications for Use

510(k) Number (if known): K070233

Device Name: Hall® Smart Guard® Irrigator

Indications for Use:

The Hall®Smart Guard® Irrigator is an accessory to a powered instrument system consisting of drills, saws and associated handpieces to perform the cutting of soft tissue and bone. The fields of application include: orthopedic, arthroscopic, neurosurgical, otolaryngological, plastic/reconstructive and oral/maxillofacial procedures.

Prescription Use √ (Part 21 CFR 801 Subpart D) AND/OR Over-The-Counter Use _____ (21 CFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K070233