K071771

>>Summary of Safety & Effectiveness

510(k) Summary as required by section 807.92(c)

date prepared 5/30/2007

AUG - 2 2007

Submission Applicant:

INSTRUMED INTERNATIONAL, INC.
626 Cooper Court
Schaumburg, IL 60173

Establishment Registration Number:

1421101

Official Correspondent:

Mr. Berndt Fetzer
INSTRUMED INTERNATIONAL, INC.
626 Cooper Court
Schaumburg, IL 60173

Phone: 847-908-0292

Trade name:
Instrumed Retractors

Common name:
Retractor

Classification name:
Retractor (21 CFR 882.4800, Product code GZT)

Substantial Equivalence Claim:

K050706; Harmony Port System, Spinal Concepts, Inc.

K992898; Bright Medical Dilation Retractor System, Bright Medical Instruments

K935529; Cervical Self-Retaining Retractor, T. Koros Surgical Instruments Corp.

K964402; Versatrac ™ Lumbar Retractor System, V. MUELLER CARDINAL HEALTH

Description of the Device:

Instrumed Retractors (frame, arm, blades, tubes) provide the surgeon with minimally invasive surgical access to the spine by ensuring the placement and positioning of the retractor posterior, anterior cervical and down to the lamina/spine, with its attachment to a rigid frame or a flexible arm to provide a self locking method of access to the spinal site through which a endoscope and/or surgical instruments can be manipulated.

>>Summary of Safety & Effectiveness

Indications for Use:

INSTRUMED retractors are devices intended to provide minimally invasive access to the spine by ensuring the placement, positioning of the retractor down to the lamina, with its attachment to a flexible arm to provide a self locking method of access to the spinal site through which tubes, endoscopes and surgical instruments can be manipulated.

Comparison with P.D.

The Instrumed product is similiar to the P.D. in terms of technical characteristics, design, Indications for Use, Target population, where it is used, performance, biocompatibility, sterilisation method, mechanical safety characteristics as well as sizes and configurations. **Therefore it can be deemed substantially equivalent and safe and effective for its indicated use.**

Summary

The presented data that was conducted on the Instrumed Retractors shows in its results and in comparison to the predicate devices that the products are absolutely safe and effective for their intended use and do not raise any new questions regarding safety and effectiveness. All models that are covered by this 510(k) premarket notification have been on the market (international) for many years with no device failures. The used materials are well researched and do not raise new questions regarding safety and effectiveness of the finished product.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

Instrumed International, Inc.
% Mr. Michael Massong
RA/QA Director
626 Cooper Court
Schaumburg, Illinois 60173

AUG - 2 2007

Re: K071771
Trade/Device Name: Instrumed Retractors
Regulation Number: 21 CFR 882.4800
Regulation Name: Self-retaining retractor for neurosurgery
Regulatory Class: II
Product Code: GZT
Dated: May 30, 2007
Received: June 29, 2007

Dear Mr. Massong:

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.

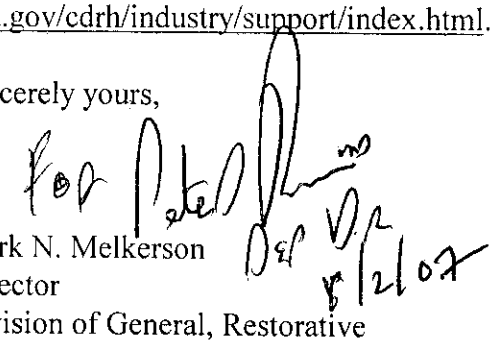
Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's 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

K071771

Indications for Use

510(k) Number (if known):

Device Name: INSTRUMED RETRACTORS

Indications For Use: INSTRUMED retractors are devices intended to provide minimally invasive access to the spine by ensuring the placement, positioning of the retractor down to the lamina, with its attachment to a flexible arm to provide a self locking method of access to the spinal site through which tubes, microscopes and surgical instruments can be manipulated.

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

510(k) Number K071771