K081651

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

date prepared 06/02/2008

Submission Applicant:

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

AUG - 8 2008

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 Rongeur

Common name:

Rongeur

Classification name:

RONGEUR, MANUAL (21 CFR 882.4840, Product code HAE)

Regulation Description

Manual rongeur.
A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.

Substantial Equivalence Claim:

K062711;	Baxano;	Ultra Low profile Rongeur
K023868;	Dannoritzer Medical Instruments;	Dan Kerrison Rongeurs, Models K1 & BILLY 1
K943635;	CARDINAL HEALTH(V.MUELLER)	Rongeurs
	K-MEDIC/TELEFLEX;	IVD Rongeurs and Spinal Punches

And many other Rongeurs marketed, some under the pre-amendment assessment rule.

Description of the Device:

A rongeur (Kerrison) is a strongly constructed instrument with a sharp-edged, scoop-shaped tip, used during laminectomy for gouging out bone and tissue.
IVD (Intervertebral Disc) Rongeurs are used on cartilage that separates adjacent vertebrae of the spine
A rongeur can be used to open a window in a bone. It is used in neurosurgery to expose areas for operation or to reduce pressure by segregating exposed areas.

To ensure the multi-purpose use of this devices, many different models are available.

Common names used for this kind of Rongeurs are:
Kerrison, Sella Punch, IVD (Decker, MIS, Spence, Peapod, Selverstone, Williams, Cushing, Love-Gruenwald, Spurling, Cloward, Sypert, Ferris-Smith, Wilde, Hoen, Oldberg, Jackson, Schlesinger)

Device description / Identification

A manual rongeur is a manually operated instrument used for cutting or biting bone during surgery involving the skull or spinal column.

All Rongeurs are offered in a non-sterile condition.

Indications for Use:

The intended use of Instrumed Rongeurs is to access, cut and bite soft tissue and bone during surgery involving the spinal column.

Performance Data

Design analysis and comparison confirm that basic functional characteristics are substantially equivalent to the P.D. cited and raise no new issues of safety and effectiveness

Comparison with P.D.

The Instrumed Rongeur 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 Rongeurs 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. 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

AUG - 8 2008

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

Re: K081651
Trade/Device Name: Instrumed Ronguer
Regulation Number: 21 CFR 882.4840
Regulation Name: Manual ronguer
Regulatory Class: II
Product Code: HAE
Dated: June 2, 2008
Received: June 12, 2008

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 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

Indications for Use

510(k) Number (if known): K081651

Device Name: Instrumed Rongeur

Indications For Use:

The intended use of Instrumed Rongeur is to access, cut and bite soft tissue and bone during surgery involving the spinal column.

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)

Concurrence of CDRH, Office of Device Evaluation (ODE)

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

510(k) Number K081651