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PETER LAZIC	510(k) Premarket Notification **Lazic Aneurysm Clips & Appliers**

K_____

510(K) SUMMARY OF SAFETY AND EFFECTIVENESS IN ACCORDANCE WITH SMDA OF 1990

DATE:
May 15, 2008

Submitted by: Peter Lazic GmbH
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DEVICES: L-Aneurysm-Clip System & L-Aneurysm Clip Appliers
Yasargil-Aneurysm-Clip System & Yasargil Clip Appliers

Device Name

Trade Name: L-Clip
Yasargil Aneurysm Clip
L-Clip Appliers
Yasargil Aneurysm Clip Aplliers

Common Name: Aneurysm Clips
Aneurysm Clip Appliers

Classification

Our aneurysm clips and aneurysm clip appliers are classified as follows:

Device:	L-Clips Yasargil Aneurysm Clips	L-Clip Appliers Yasargil Aneurysm Clip Appliers
Device description:	Aneurysm clip	Aneurysm clip applier.
Medical Specialty:	Neurology	Neurology
Product Code:	HCH	HCI
Regulation Number:	882.5200	882.4175
Device Class:	2	2

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Substantial Equivalence

Lazic's Aneurysm Clips and Aneurysm Clip Appliers are substantial equivalent to similar devices distributed by KIRWAN (KIRWAN L-Aneurysm Clips and Appliers), Rebstock GmbH (REBSTOCK Aneurysm Clips), Von Zeppelin GmbH (Perneczky Aneurysm Clips, Perneczky Clip Applier/Remover), Aesculap, Inc. (Yasargil Clip Appliers).

Description of the Device

L-Aneurysm Clips and Yasargil-Aneurysm Clips are available in two principle sizes (Standard and Mini) and several forms of jaws (straight, curved, angled, bayonet, fenestrated, non-fenestrated). Both sizes are available for permanent or temporary occlusion.

L-Aneurysm Clip Appliers are designed to be used with both principle sizes of L-Aneurysm Clips. Yasargil Clip Appliers are available in two principle sizes (Standard and Mini), matching the respective size of the applied Yasargil Aneurysm Clip.

Intended Use

Aneuysm Clips

Permanent L-Aneurysm-Clips and YASARGIL aneurysm and vessel clips are intended for permanent occlusion of blood vessels and cerebral aneurysms. Likewise, temporary L-Aneurysm-Clips and Yasargil aneurysm and vessel clips are intended for temporary occlusion of intra cranial blood vessels and cerebral aneurysms.

Aneurysm Clip Applying Forceps

The L-Aneurysm-Clip Appliers are intended to be used for holding and applying L-Aneurysm-Clips.

The Yasargil-Aneurysm-Clip Appliers are intended to be used for holding and applying Yasargil-Aneurysm-Clips.

The L-Aneurysm-Clip Appliers and the Yasargil-Aneurysm-Clip Appliers are not compatible to other traded systems.

Performance Standards

The devices are conforming to following standards:
ASTM F1542-94(2000), ASTM F2129(2004), ISO 9713

Sterilization

Lazic's L-Aneurysm Clips and Yasargil Aneurysm Clips are available in sterile or non sterile conditions. Lazic's Aneurysm Clip Appliers are available in non-sterile conditions only.

Conclusion

Based on the available 510(k) summaries and 510(k) statements (21 CFR 807) and the information provided herein, we conclude that Lazic's L-Aneurysm Clips and Appliers as well as Yasargil Aneurysm Clips and Appliers, are substantially equivalent to the existing legally marketed devices under Federal Food, Drug and Cosmetic Act.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

SEP 2 5 2008

Peter Lazic GmbH
c/o Mr. Franz Menean
Griesweg 47
D-78570 Mühlheim
Germany

Re: K081489
Regulation Number: 21 CFR 882.5200
Regulation Name: Aneurysm Clip
Regulatory Class: Class II
Product Code: HCH
Dated: September 21, 2008
Received: September 24, 2008

Dear Mr. Menean:

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

K081480

Indications for Use

510(k) Number: K_____

Device Name:

L-Aneurysm-Clip system & Appliers / Yasargil-Aneurysm-Clip system & Appliers

Indication for Use – Aneuysm Clips

Permanent L-Aneurysm-Clips and YASARGIL aneurysm and vessel clips are intended for permanent occlusion of blood vessels and cerebral aneurysms. Likewise, temporary L-Aneurysm-Clips and Yasargil aneurysm and vessel clips are intended for temporary occlusion of intra cranial blood vessels and cerebral aneurysms.

Indication for Use – Aneurysm Clip Applying Forceps

The L-Aneurysm-Clip Appliers are intended to be used for holding and applying L-Aneurysm-Clips.

The Yasargil-Aneurysm-Clip Appliers are intended to be used for holding and applying Yasargil-Aneurysm-Clips.

The L-Aneurysm-Clip Appliers and the Yasargil-Aneurysm-Clip Appliers are not compatible to other traded systems.

Prescription Use __**YES**___ AND/OR Over-The-Counter Use __**NO**__
(Part 21 CFR 801 Subpart D) (21 SFR 801 Subpart C)

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

Concurrence of CDRH, Office of Device Evaluation (ODE)

Mark N Milhan

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

510(k) Number K081489