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K962952

510(K) SUMMARY OLYMPUS ULTRASOUND SURGICAL SYSTEM

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR §807.92.

The assigned 510(k) number is: K962952

Device Name: Olympus Ultrasonic Surgical System

Common/Usual Name: Olympus USU

Classification Name: Ultrasonic Surgical System/Ultrasonic Aspirator

Predicate Devices: Cavitron Ultrasonic Surgical Aspirator CUSA® Type NS-100 (K#801623)
CUSA® System 200c/200t/200m/200h Ultrasonic Aspirator (K#910696)
CUSA® System 200c and 200t Ultrasonic Aspirator (K#921251)
Cooper Laser Sonics CUSA® Model 200 (K#950945)
Sharplan ULTRA Ultrasonic Aspirator (K#883091)

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Summary Preparation

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Statement of Intended Use:

The intended use of the Olympus USU is identical to the currently marketed CUSA® system 200 which was cleared for marketing in 510(k)#s K#910696 and K#921251.

Both systems are used for smashing and aspirating disease tissues in the Neuro surgery field.

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Thus, when compared to the predicate device, the Olympus USU does not raise any questions regarding the safety to the subject device.

The Olympus Ultrasonic Surgical System is indicated for use in the fragmentation, emulsification, and aspiration of soft tissue in the neurosurgery field.

Device Description:

The Olympus USU is specially designed for open procedure in the Neurosurgery field, in order to smash and aspirate disease tissue such as cerebral tumor, cerebral hematoma, cerebral aneurysm/varicosity.

The predicate devices for this system are the following:

- a. Cavitron Ultrasonic Surgical Aspirator CUSA® Type NS-100 (K#801623)
- b. CUSA® System 200c/200t/200m/200h Ultrasonic Aspirator (K#910696)
- c. CUSA® System 200c and 200t Ultrasonic Aspirator (K#921251)
- d. Cooper Laser Sonics CUSA® Model 200 (K#950945)
- e. Sharplan ULTRA Ultrasonic Aspirator (K#883091)

Actuation mechanisms of the above systems is the same as the USU based as the following:

The small ultrasound vibration which is generated by the ultrasound actuator built-in hand piece, is transferred to the probe which is mounted on the edge of hand piece. The tissue is smashed by the shock force exchanged from the vibration on the probe with pushing to the tissue.

The smashed tissue is taken out by the suction space between the probe and sheath of hand piece.

The Olympus USU mainly is used in microscopic surgery.

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General Safety:

The Olympus USU is designed, manufactured and tested in compliance with Voluntary Safety Standards. It meets the requirements of IEC 601-1 and 601-1-2, as well as CISPR 11.

When compared to the predicate devices, the Olympus USU does not incorporate any significant changes in intended use, method of operation, material, or design that could affect the safety or effectiveness.