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K955012

510(k) SUMMARY

Mizuho Radiolucent Head Frame

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Trade Name: Mizuho Radiolucent Head Frame
Common Name: Skull Clamp or Head Holder
Classification Name: Neurosurgical Head Holder (Skull Clamp)

Legally Marketed Devices to Which Substantial Equivalence is claimed:

Malcolm-Rand Radiolucent Headrest
Sugita Multi-Purpose Head Frame

510(k) SUMMARY-continued
Mizuho Radiolucent Head Frame

Description of Device: The device uses a four (4) point system to clamp a patient's head during surgical procedures. The material used was selected to reduce or eliminate interference normally associated with all metal skull clamps should x-rays or similar diagnostic activity be utilized during the procedure.

Intended Use of the Device: Clamping of a patient's head and neck in a particular position during surgical procedures.

Summary of Technological Characteristics: The four (4) point systems is found in each of the legally marketed devices to which substantial equivalence is claimed. The devices components will function in conjunction with operating table attachments currently marketed by Mizuho America. The radiolucent characteristic is similar to that which is found in the Malcolm-Rand system. In each system, the main components are carbon fiber. The Malcom-Rand system uses disposable pins which are attached to the end of the four (4) screws while the proposed Mizuho device will have reusable pins which are a combination of metal and non-metal.

Summary of test data:

Deflection Under Load: The device was assembled onto an operating table and loads applied. The metal device was subjected to the same test procedure. The results show that the devices deflect essentially the same amount.

Durability of Reusable Skull Pins: Testing of sample skull pins was conducted in which they were processed in a hospital using a normal high temperature pre-vacuum cycle for that hospital, 274°F for four (4) minutes. Pins were removed after 5, 10, 20 and 40 cycles for destructive testing. There was essentially no change in the results compared with unprocessed pins. The break load during all testing was substantially higher than that which is used in surgical procedures.

Radiolucence: Representative x-rays included in advertising show that the interference resulting from the use of this device is minimal.