

K961601

Attachment 2

Premarket Notification [510(k)] Summary

DEC 23 1996

Trade Name: H.A.M. Applicator

Common Name: Applicator for remote controlled afterloading brachytherapy

Classification Name and Number: Remote controlled radionuclide applicator system (accessory), JAQ (per 21 CFR 892.5700)

Class II, Radiology Panel (90)

Description: The H.A.M. (Harrison-Anderson-Mick) Applicator system consists of the H.A.M. Applicator, the H.A.M. Sandwich (a clamping device) source-guide tubes, when required by certain HDR systems, and a Martin Arm/Clamp (a preamed device manufactured by Martin Medizin-Technik) which attaches the H.A.M. Sandwich to the operating table. The H.A.M. Applicator is manufactured from liquid silicone rubber and contains between three and twenty-four embedded hollow tubes. The tubes are spaced 1cm on center laterally and are positioned 5mm from the treatment surface.

Intended Use: The H.A.M. Applicator is intended to be used as an accessory to high-dose-rate (HDR) remote controlled radionuclide applicator systems cleared for market by the FDA. The H.A.M. Applicator may be used externally, on the surface of the patient, to treat superficial tumors or placed internally to treat the tumor or tumor bed in a procedure known as Intraoperative High-Dose-Rate Brachytherapy (IOHDR) [a subset of Intraoperative Radiation Therapy (IORT)], during the time the treatment site is exposed surgically.

Technological Characteristics: The technological characteristics of the H.A.M. Applicator and the predicate device are the same in that both are meant to position radioactive sources in a specific, known geometrical relationship to the treatment volume as prescribed by the physician.

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Date: 22 September 1996