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510 (k) SUMMARY

**MITSUBISHI LINEAR ACCELERATORS
EXL SERIES**

1. Submitter:

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2. Device Name:

The 510 (k) submission is for EXL series of Mitsubishi Linear Accelerators utilizing klystron and magnetron power supplies and computerized control consoles.

3. Predicate device:

The devices described in this submission are considered to be substantially equivalent to the EXL series of Mitsubishi Linear Accelerators utilizing klystron and magnetron power supplies and conventional hard-wired control consoles. The predicate device are legally marketed, having been found to be substantially equivalent through the 510 (k) premarket notification process.

4. Device description:

Medical Linear Accelerators provide a high energy beam of electrons and/or x-rays which is used for the treatment of cancer. The beam produced by the machine is carefully controlled in terms of geometry, energy, uniformity and intensity. The device also provides mechanisms for positioning the patient and controlling the delivery geometry.

The accelerators consist of three major subsystems, the Control Console, Gantry Stand, and Rotating Gantry.

The control console is the main component for operation and control of the LINAC. It is used to select the machine operation and patient treatment parameters and monitor the machine operating conditions. The new control console for the EXL-DP series of accelerators consists of an operator keyboard, video display, and various computers and control circuits.

The Gantry Stand contains the high power sources for the accelerator system, notably the Klystron microwave power, modulator and electromagnet power supplies.

The Rotating Gantry contains the accelerating tube, energy switching system, beam bending magnet, x-ray target, collimator, dosimetry system, and various safety features and circuits.

5. Intended use:

The EXL series of accelerators are intended to be used for electron or photon radiation treatment of cancer.

6. Comparison of technological characteristics:

This submission describes the modification of existing Mitsubishi EXL series of accelerators by the replacement of the conventional hard-wired operator console with the computerized console. There has been no change to the traditional treatment beam control circuit, dosimetry monitor circuit and interlock circuit from the currently marketed LINACS. Likewise, there has been no change in the function or performance specifications or characteristics. The technology used to set the operating parameters is transparent to the gantry and gantry stand where actual beam generation and delivery takes place.