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510(k) Summary

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DEVICE COMMON OR USUAL NAME..... Laser Film Recorder

DEVICE PROPRIETARY NAME..... LR 5200 Laser Film Recorder

SUBSTANTIAL EQUIVALENCE DEVICES... (CLASS II DEVICE) AGFA LR 3300
AGFA COMPACT L
DUPONT LP 400
FUJI FL-IMD
POLAROID HELIOS 1417

DEVICE DESCRIPTION..... The LR 5200 is a laser based (Helium-neon) film recorder, designed for producing high quality gray scale diagnostic medical images, when interfaced to a host imaging device. Typical host imaging devices would include those of Magnetic Resonance, Computed Tomography, Ultrasound, Mammography, Digital Radiography, and Nuclear Medicine imaging modalities. The diseases and conditions that the device will aid in the diagnosis of, are those that are typical to radiological types of examinations.

TECHNOLOGICAL CHARACTERISTICS.... The LR 5200 has the same technological considerations as those mentioned above in the Substantially Equivalent Device section. These are a light source that becomes modulated with the patient image information and then written on a photo sensitive medium for viewing by the diagnosing physician.