DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

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See PRA Statement below.

510(k) Number *(if known)*

K180592

Device Name

G-Scan Brio

Indications for Use *(Describe)*

G-scan Brio is a Magnetic Resonance (MR) system that produces transversal, sagittal and coronal and oblique cross-section images of the head, limbs, joints and spinal column. It is intended for imaging the head, imaging portions of the upper limb, including the hand, wrist, forearm, elbow, arm and shoulder, imaging portions of the lower limb, including the foot, ankle, calf, knee, thigh and hip, imaging the temporomandibular joint and imaging the cervical, the thoracic and the lumbosacral sections as portions of the spinal column.

G-scan Brio images correspond to the spatial distribution of protons (hydrogen nuclei) that determine magnetic resonance properties and are dependent on the MR parameters, including spin-lattice relaxation time (T1), spin-spin relaxation time (T2), nuclei density, flow velocity and "chemical shift". When interpreted by a medical expert trained in use of MR equipment, the images can provide diagnostically useful information.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

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