510(k) Summary

The following 510(k) summary has been prepared pursuant to requirements specified in 21CFR 807.92(a).

Submitter Information

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Trade Name: G-scan Brio

Classification Panel: Radiology

Classification Name(s): Magnetic Resonance Diagnostic Device

Classification Number: 90LNH

Predicate Device(s)

Trade Name	Common name	Class	Product code	Manufacturer	K number
G-scan Brio	System, nuclear magnetic resonance imaging	II	LNH	ESAOTE S.P.A.	K161973

Reference Device(s)

Trade Name	Common name	Class	Product code	Manufacturer	K number
OrthoCAD System	System, Image Processing, Radiological	II	LLZ	ESAOTE S.P.A.	K120288
3Viseon/ Surgery	Picture Archiving Communications System	II	LLZ	3MENSIO MEDICAL IMAGING BV	K072653

Device Description

The changes performed on the modified G-scan Brio, with respect to the cleared version – G-scan Brio K161973 – are due to the upgrade of the software system. These modifications, which do not affect the intended use or alter the fundamental scientific technology of the device, are the following:

- A new Software version (EVO'17) including the following features:
    - New software feature Q-Spine (Quantitative Spine)
    - New software feature 3D Viewer
    - The availability of the E-MRI viewer eXP, the software used as an extension on PC.

Esaote has decided to develop and release an upgrade for software EVO. The EVO'17 includes two new features Q-Spine and 3D Viewer. The function Q-Spine has been already cleared by FDA under the name OrthoCAD System via K120288. The function 3D Viewer has been already cleared by FDA under the name 3Viseon/Surgery via K072653. E-MRI viewer eXP, the software used as an extension on PC, is equivalent to E-MRI Brio Viewer, which is currently available on the G-Scan Brio MRI systems, cleared via K161973.

Intended Use(s)

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.

Technological Characteristics

The technological characteristics of the G-scan Brio systems with the addition of Q-Spine, 3D Viewer, and availability of E-MRI viewer eXP, reflected in this 510(k), do not alter the scientific technology of the G-scan Brio systems and are substantially equivalent to those of the predicate devices. The modification are implemented in order to improve display, analysis and comparison of Magnetic Resonance images.

Summary of Non-Clinical Tests

The G-scan Brio has been evaluated to demonstrate substantial equivalence related to medical electrical equipment, risk management, and software verification and validation and has been found to conform to the following medical device safety standards:

- IEC 60601-1
- IEC 60601-1-2
- IEC 60601-1-6

- IEC 60601-2-33
- ISO 14971
- ISO 62304
- IEC 62366
- NEMA MS-1
- NEMA MS-3

Summary of Clinical Tests

No clinical tests are included within this submission.

Conclusion

The non-clinical testing demonstrates that the G-scan Brio is as safe, as effective, and performs as well as or better than the predicate. G-scan Brio is substantially equivalent to the legally marketed devices and conforms to applicable medical device safety and performance standards.