

SUMMARY OF SAFETY AND EFFECTIVENESS

I. General Information

Classification: Class II
Magnetic Resonance (MR) Imaging System

Common/Usual Name: MRI System Option

Proprietary Name: EPI-II System Option with High Performance Gradients

Establishment Registration: Picker International, Inc.
World Headquarters
595 Miner Road
Cleveland, Ohio 44143
FDA Owner Number: #1580240
FDA Registration Number: #1525965

Performance Standards: Not applicable

2. **Intended Uses:** The EPI-II System Option with High Performance Gradients is designed to provide higher gradient output power in order to allow the user to acquire images at a faster rate or acquire images with a higher spatial resolution than would normally be possible with a standard EDGE system with the EPI-I software option. The indications for use are the same as for standard MR imaging.

3. **Device Description:** The EPI-II System Option with High Performance Gradients consists of water-cooled non-resonant self-shielded gradient coils, high performance gradient amplifiers, single-shot echo-planar sequences, and modified standard sequences.

4. Safety and Effectiveness

a. Safety

As shown in the chart below, the Picker EPI-II System Option with High Performance Gradients for an EDGE system is identical to the standard EDGE system using the EPI-I multi-shot software option except for the dB/dt operating levels and software algorithm.

SAFETY CHART

Parameter	EDGE with EPI-II System Option	EDGE with EPI-I Software Option
Static Magnetic Field Corresponding to proton resonance of 63.75 MHz (EDGE).	Same	Same
Time Varying Magnetic Field	Total dB/dt software algorithm warns when operational level is above 40 T/s and prohibits operation above 60 T/s (as measured by method in FDA's draft guidance document).	Not to exceed 20 T/s (as measured according to method in IEC 601-2-33).

Parameter	EDGE with EPI-II System Option	EDGE with EPI-I Software Option
<p>Radio Frequency Absorption</p> <p>Power deposition during imaging is limited by the SAR algorithm to a maximum value of:</p> <p>1.2 W/kg NORMAL OPERATING MODE 2.4 W/kg FIRST LEVEL CONTROLLED OPERATING MODE > 2.4 W/kg SECOND LEVEL CONTROLLED OPERATING MODE (Requires human studies protocol approval according to local requirements.)</p>	Same	Same
Acoustic Noise	Acoustic noise levels of EPI-II System Option under worst case conditions are: 109.1 dBA (average) and 119.5 dB (peak).	Acoustic noise levels of standard EDGE system under worst case conditions are: 118.7 dBA (average) and 127.8 dB (peak).

Parameter	EDGE with EPI-II System Option	EDGE with EPI-I Software Option
<p data-bbox="245 312 428 343">Intended Use:</p> <p data-bbox="245 380 586 1097">The Picker International EDGE system is indicated for use as a NMR device that produces images that: (1) correspond to the distribution of protons exhibiting NMR, (2) depend upon the NMR parameters (proton density, flow velocity, spin-lattice relaxation time (T1), and spin-spin relaxation time (T2)) and (3) display the soft tissue structure of the head and whole body. When interpreted by a trained physician, these images yield information that can be useful in the determination of a diagnosis.</p>	<p data-bbox="618 312 688 343">Same</p>	<p data-bbox="998 312 1068 343">Same</p>

b. Effectiveness

Compared to the standard EDGE system using the EPI-I software option (see 510(k)s K931544 and K945828), the EPI-II System Option has a gradient system which is able to produce higher gradient operational levels and provide faster scanning capability. The EPI-II System Option also includes EPI single shot sequences.

EFFECTIVENESS CHART

Parameter	EPI-II System Option	Predicate
Gradient Coil Design	Water-cooled, high performance, self-shielded non-resonant gradient system.	Basic EDGE system uses a standard performance, air cooled, self-shielded gradient system. (see 510(k) K931544).
Gradient Power	Gradient Amplifiers: 270 A RMS, 440 A peak, 600 V max.	Gradient Amplifiers: 135 A RMS, 220 A peak, 350 V max. (see 510(k) K931544)
Gradient Performance	Maximum Gradient Strength = 27 mT/m Maximum Slew Rate = 72 mT/m/msec	Maximum Gradient Strength = 16 mT/m Maximum Slew Rate = 25 mT/m/msec
Fast Scanning Sequences	Single-shot EPI fast scanning sequences. Entire image collected following a single RF excitation using multiple gradient recalled echoes.	Multi-Shot EPI fast scanning sequences. A number of RF excitations are required to collect an entire image. Multiple gradient recalled echoes used to collect data. (see 510(k) K945828)
EPI Data Correction	Interactive prescan process.	Automated process which does not require operator involvement. (see 510(k) K945828)
IR Prep Pulse	Improves T_1 image contrast.	Same. (see 510(k) K945828).
Standard Imaging Sequences	Increased image resolution or redesigned for: shorter inter-echo spacing; shorter echo times; and/or increase motion artifact suppression.	Standard image resolution, inter-echo spacing, echo times, and motion artifact suppression, limited by the lower output power of the gradient system.