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510(k) Summary K961391

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Classification Name: Magnetic Resonance Device Accessory - QD Head and Neck Coil
Classification: Class II-90LNH, per 21 CFR 892.1000
Common Name: Head and Neck Coil
Proprietary Name: Flexart Head and Neck Coil
Model Name: MRT-50GP

Establishment Registration Number: 2936923

Applicable Performance Standards:

None, although this device follows the requirements of the current Guidance for the Content and Review of a Magnetic Resonance Diagnostic Device 510(k) Application.

Substantial Equivalence Summary:

The Flexart™ Head and Neck Coil is essentially a QD (quadrature) extension of the standard receive only Cervical Collar cleared with the Flexart. The extension consists of adding a figure-8 planar loop onto the printed circuit coil trace board, so that there are now two independent RF loops (one rectangular and one figure-8). The RF magnetic fields from the two loops are oriented at 90 degrees with respect to each other (in quadrature).

The two loops are matched in impedance and tuned to the imaging system's center frequency by using varactors and the RF outputs are then amplified with low noise amplifiers. The active decoupling of the coil during transmit is achieved by use of two (one for each loop) high impedance parallel resonant traps which are activated by diodes. These diodes turn on because of the inductively coupled voltage from the transmitter coil's RF magnetic field.

The Flexart Head and Neck Coil does not change the previously cleared safety parameters of the Flexart system and standard QD C-Spine Coil. Manufacturing methods and software verification and validation procedures for the Flexart system and standard QD C-Spine Coil remain unchanged.

Safety Parameters

Maximum Static Field Strength	0.5Tesla
Rate of Change of Magnet Field:	6.97 T/s axial, 10.64 T/s transverse, with T> 700 microseconds
Radiofrequency Power Depostion:	0.256 W/kg
Acoustic Noise Levels:	89.5 - 94.5 Typical

Note: Safety parameters of the Flexart are not changed from those cleared in the MRT-50GP 510(k) K933018.

Imaging Performance Parameters

1. Specification volume:	10 cm dsv	
2. Signal to Noise Ratio (typical):	Transaxial:	73.2
	Coronal:	62.3
	Sagittal:	61.2
3. Uniformity:	Not Applicable	
4. Geometric Distortion:	Not Applicable	
5. Slice profile in the orthogonal planes:	Not Applicable	
6. Slice thickness:	Not Applicable	
7. Interslice spacing:	Not Applicable	

Indications for Use

General disease and vascular imaging of the head and cervical regions