Appendix A

510(k) Summary

K961624

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Submitter: Toshiba America MRI, Inc.
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Classification Name: Magnetic Resonance Device Accessory - Bilateral TMJ Coil

Classification: Class II-90LNH, per 21 CFR 892.1000

Device Tier: 2, according to the December 15, 1993 DRAERD Triage Pilot Program

Common Name: Bilateral TMJ Coil

Proprietary Name: Flexart™ Bilateral TMJ Coil

Model Name: Flexart™

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 new Flexart™ Bilateral TMJ Coil is compared to the 100mm surface coil cleared with the Flexart™ 510(k) K933018 and the MRT-150A Bilateral TMJ Coil cleared in K943021. The coils share similar Signal-to-Noise ratios, attachment schemes, tuning and detuning schemes and safety parameters. The Flexart™ Bilateral TMJ Coil does not change the previously cleared safety parameters of the Flexart™ system. Manufacturing methodology and software verification and validation procedures for the Flexart™ remain unchanged. Patient contact materials are the same as those previously cleared for other Toshiba coils.

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 head, 20 cm dsv body	
2. Signal to Noise Ratio (typical):	Transaxial:	167
	Coronal:	154
	Sagittal:	224
3. Uniformity:	Unchanged	
4. Geometric Distortion:	Unchanged	
5. Slice profile in the orthogonal planes:	Unchanged	
6. Slice thickness:	Unchanged	
7. Interslice spacing:	Unchanged	

Indications for Use

General disease of the TMJs