Supplementary Table 1. Product Code Classifications

Classification	Product Code	Description	Classification	Product Code	Description
External Beam			*Brachytherapy*		
	IYE	Accelerator Linear Medical		KPT	Calibrator Dose Radionuclide
	MWW	Accessory - Film Dosimetry System		ONL	Conformal Brachytherapy Source
	ITZ	Assembly Tube Housing X-Ray Therapeutic		MOU	Intravascular Radiation Delivery System
	IYG	Betatron Medical		NAW	Microspheres Radionuclide
	IXI	Block Beam-Shaping Radiation Therapy		IWF	Needle Isotope Gold Titanium Platinum
	IYL	Collimator Dermatological Therapeutic X-Ray		NMP	Needle Isotope Reprocessed
	IYK	Collimator High Voltage Therapeutic X-Ray		PCT	Prostate Immobilizer Rectal Balloon
	IYJ	Collimator Low Voltage Therapeutic X-Ray		OIN	Prostate Seeding Kit
	IYI	Collimator Orthovoltage Therapeutic X-Ray		IWG	Seed Isotope Gold Titanium Platinum
	JAI	Couch Radiation Therapy Powered		KXK	Source Brachytherapy Radionuclide
	IWK	Cyclotron Medical		IXD	Source Calibration Sealed Nuclear
	IWD	Device Beam Limiting Teletherapy Radionuclide		IWI	Source Isotope Sealed Gold Titanium Platinum
	KQA	Device Beam Limiting X-Ray Therapeutic		IWA	Source Wire Iridium Radioactive
	NZT	Dosimeter Ionizing Radiation Implanted		IWJ	System Applicator Radionuclide Manual
	IYH	Generator Dermatological (Grenz Ray) Therapeutic X-Ray		JAQ	System Applicator Radionuclide Remote-Controlled
	KPZ	Generator High Voltage X-Ray Therapeutic			
	IYD	Generator Low Voltage Therapeutic X-Ray	*Software*		
	IYC	Generator Orthovoltage Therapeutic X-Ray		MUJ	System Planning Radiation Therapy Treatment
	JAE	Microtron Medical			
	IWE	Monitor Patient Position Light-Beam	*Simulation*		
	IWH	Source Teletherapy Radionuclide		KPQ	System Simulation Radiation Therapy
	IWM	Synchrotron Medical			
	LHN	System Radiation Therapy Charged-Particle Medical			
	IWL	System Radiation Therapy Neutron Medical			
	IWB	System Radiation Therapy Radionuclide			
	JAD	System Therapeutic X-Ray			

Supplementary Table 2. FDA Determined Cause Classifications‡

Classification	FDA Determined Cause	Classification	FDA Determined Cause
Component		*Other/Under Investigation*	
	Component change control		Other
	Component design/selection		Pending
			Under Investigation by firm
*Device Design/Change Control**			Unknown/Undetermined by firm
	Device Design		
	Finished device change control	*Packaging*	
			Package design/selection
Employee/Use Error			Packaging
	Employee error		Packaging change control
	Use error		Packaging process control
Equipment maintenance		*Process*	
	Equipment maintenance		Process change control
			Process control†
Labeling			Process design
	Error in labeling		
	Labeling Change Control	*Software*	
	Labeling design		Software change control
	Labeling False and Misleading		Software design
	Labeling mix-ups		Software design (manufacturing process)
	Incorrect or no expiration date		Software Design Change
			Software in the Use Environment
Material/Component			Software Manufacturing/Software Deployment
	Nonconforming Material/Component		
	Manufacturing material removal	*Radiation Control for Health and Safety Act*	
	Material/Component Contamination		Radiation Control for Health and Safety Act
	Mixed-up of materials/components		
	Release of Material/Component prior to receiving test results		

* Change control means formal processes used within quality management systems (QMS) to ensure that changes to a product or system are introduced in a controlled and coordinated manner.
† Process control entails developing, conducting, controlling, and monitoring production processes to ensure that a device conforms to its specifications.
‡ For brevity, the following determined causes were omitted, as 0% of ROD recalls and <0.4% of other device recalls cited them: Counterfeit, Environmental control, PMA, Reprocessing Controls, Storage, Vendor change control