510k's

510k Number	Company	Product Code	Device Type	Status
K180292	Pentax Medical	FDS	EG34-i10	Written/Cleared
K180285	Pentax Medical	FDF	EC34-i10T Series	Written/Cleared
K173679	Pentax Medical	PEA/EOQ	PENTAX Medical EPK-i7010 Video Processor with EB Family of Scopes	Written/Cleared
K173544	Pentax Medical	EOB/EOB	Video Bronchoscopes	Written/Cleared
K172156	Pentax Medical	EOB/PEA	PENTAX Medical EPK-3000 Video Imaging System	Written/Cleared
K171011	Pentax Medical	EOB	Flexible Video Rhino-Laryngoscope System	Written/Cleared
K161222	Pentax Medical	FDT	ED-3490TK Video Duodenoscope	Written/Cleared
K171259	Surgical Lasers Inc.	GEX	Surgical Laser	In - Process
K171730	Non-Friction Products	NUC	Personal Lubricant	Written/Cleared
K163030	Flared Patch Medical	FTL	Surgical Mesh	In-Process
K162977	Siemens Healthcare Diagnostics	GZK	Automated Hematology Analyzer	Written/Cleared
K161322	ZepMed	LLZ	PACS System	Written/Cleared
K151613	Boston Scientific	IYO	Ultrasonic Pulsed Ultrasonic Imaging System	3rd Party Reviewed for FDA/Cleared
K151867	Diagnostica Stago	JPA	In-Vitro Diagnostic	Written/Cleared
K152032	Azena Dental	GEX	Dental Laser	3rd Party Reviewed for FDA/Cleared
K142054	ImaCor, Inc.	IYN, IYO, ITX	Ultrasonic Doppler Ultrasonic Imaging System	Written/Cleared
BK130050	BioArray Solutions, Ltd	JJY	Positive Control Assay	Written/Cleared
BK130051	BioArray Solutions, Ltd	NSU	Array Imaging Systems	Written/Cleared
K100236	Stair Systems	LLZ	PACS System	Written/Cleared
K083455	Medi-Kahn	MUU	Liposuction Device	Written/Cleared
K087207	MedX Electronics	ILY	Tethered Laser	3rd Party Reviewed for FDA/Cleared
K083030	EMSI	GZJ/IPF	TENS Device	3rd Party Reviewed for FDA/Cleared
K082816	GE Medical Systems	JAK	Computed Tomography X-ray System	3rd Party Reviewed for FDA/Cleared
K081905	Accuflow and Accuflux Elastomeric Infusion Pump	MEB	Infusion Pump	3rd Party Reviewed for FDA/Cleared

510(k)'s (cont'd)

K081215	Kjaya Medical	LLZ	PACS System	3rd Party Reviewed for FDA/Cleared
K081985	GE Medical Systems	LLZ	PACS System	3rd Party Reviewed for FDA/Cleared
K081644	Conmed	GEI	Electrosurgical Device	3rd Party Reviewed for FDA/Cleared
K081841	Amplivox	ETY	Auditory Test Impedance	3rd Party Reviewed for FDA/Cleared
K081916	GE Medical Systems	LNH	MRI System	3rd Party Reviewed for FDA/Cleared
K081143	Biomers	DYW/DZC	Orthodontic Bracket	3rd Party Reviewed for FDA/Cleared
K081028	GE Medical Systems	LNH	MRI System	Written/Cleared
K080290	American Radiologist Network	LLZ	PACS System	3rd Party Reviewed for FDA/Cleared
K052200	MR Instruments	MOS	MRI RF Coil	Written/Cleared
K040937	MR Instruments	MOS	MRI RF Coil	Written/Cleared
K031089	WL Gore & Associates	MOS	MRI RF Coil	Written/Cleared
K023679	WL Gore & Associates	MOS	MRI RF Coil	Written/Cleared
K013810	WL Gore & Associates	MOS	MRI RF Coil	Written/Cleared

Pre-Submissions/PMA Supplements

Type	Company	Device	FDA Division	Status
Q162079	Ducoret	Uterine Compressor	CDRH	Accepted
P000021(31)/ P020027(26)	Siemens Healthcare Diagnostics	TPSA/FPSA Assay	CDRH	Approved May 2017
Q170859	Innovation Unlmtd	Tracheostomy Alarm	CRDH	Accepted

PMA's

PMA #	Company	Device	FDA Division	Status
BP130026	BioArray Solutions Ltd	HEA BeadChip In-Vitro Diagnostic	CBER	Approved May 2014

Regulatory Submission Summary

Regulatory Body	Regulatory Submission	Status	Quantity
US FDA	PMA	Written/Approved	1
US FDA	510(k)	Written/Cleared	22
US FDA	510(k)	3rd Party Review	13
		In Process	2
Total Regulatory Submissions			**37**