



Clinical Devices & Diagnostics

Coupled with drugs and treatments are the technologies used to diagnose and deliver those drugs. In order to fully determine that an infection is present in the body, for example, a series of blood tests and physical tests must be run by a physician. The test used to determine the presence of infection is a diagnostic tool. Most treatable disease indications will have an associated diagnostic tool. After the presence of infection has been determined, drugs need to be administered to the patient by the use of a device. Many devices are being developed to facilitate easier and more efficient drug delivery.

W
A
C
A
C
T

Accessories

Accessories are temporary devices that are implanted in the body to treat disorders. They often serve as drug delivery vehicles or as implanted diagnostics tools regulating or relaying information on organ function.

Indication	Company	Product	Phase
Accessories	Cardima Inc	Intellitemp	M
	Cardima Inc	Naviport	M
	Cardima Inc	Venaport	M
	Cardima Inc	Vueport	M

Adjunct Technologies

Adjunct technologies work in concert with existing device and diagnostic tools by stimulating a metabolic response. While conventional mechanisms for various responses do exist, they are often more invasive and have more side effects. This new technology potentially could make it easier and faster for healthcare providers to administer the pharmacologic agent and perform the needed imaging test.

Indication	Company	Product	Phase
Dysfunctional Hemodialysis	Genentech Inc	TNKase (tenecteplase)	III
Adjunct	AcroMetrix	OptiQual	M
Cell and Media Systems	Ventria Bioscience	Cellastim	M
	Ventria Bioscience	Lacromin	M
Adjunct	CV Therapeutics Inc	Regadenoson / CVT-3146	PA

Clinical Systems

Clinical Systems are products that assist in the storage, diagnostics and protection of bodily fluids used for transfusion. They serve to limit the infection of transfused fluids such as blood and platelets.

Indication	Company	Product	Phase
Clinical Systems	Cerus Corp	Intercept Blood System for Plasma	III
	Cerus Corp	Intercept Blood System for Platelets	III
	Xtent Inc	Custom NX System	III
	Cardima Inc	REVELATION Tx Microcatheter System	PA
	Cardica Inc	C-Port Flex A Anastomosis System	A
	Diamics Inc	CerCol Cervical Sample Collection System	A
	Reliant Technologies	Fraxel re: fine Laser System	A
	Thermogenesis Corp	CryoSeal FS System	A
	BioCheck Inc	dotLab System	M
	Accuray Inc	CyberKnife	M
	Accuray Inc	CyberKnife System	M
	Cardiva Medical Inc	Boomerang Catalyst System	M
	Fluidigm Corp	BioMark System	M
	McKesson Corp	Horizon Anatomic Pathology	M
Micrus Endovascular Corp	Cashmere Microcoil System	M	

Diagnostics

Diagnostics tools play a critical role in health management and the early detection of disease. Diagnostics tools work inside the body on the microscopic level to detect early signs of disease or are a part of laboratory testing outside the body. They work often by detecting changes in chemical concentrations or identifying and illuminating organs to enhance study by outside diagnostics tools (such as MRI machines). The information from these tests and procedures provides patients and healthcare providers specific information about the status of diseases or disorders.

Company	Product	Phase	Indication
Bayer HealthCare	BX471	II	Diagnostics
Bayer HealthCare	Feridex I.V (ferumoxides)	M	
Bayer HealthCare	Magnevist Injection (gadopentetate dimeglumine)	M	
Bayer HealthCare	Ultravist (iopromide)	M	
Cardima Inc	Pathfinder	M	
Cardima Inc	Pathfinder Mini	M	
Cardima Inc	Revelation	M	
Cardima Inc	Tracer	M	
Cholestech Corp	Cholestch GDX System	M	
Cholestech Corp	LDC System (TC)	M	
Cholestech Corp	LDX Analyzer	M	
Cholestech Corp	LDX Styem	M	
Cytec Corp	FullTerm	M	
HemoSense Inc	INRatio	M	
Pharmagenesis Inc	Feridex I.V (ferumoxide)	M	
Ventria Bioscience	Lysobac	M	

Implants

The course of disease often damages bodily tissues such that they must be removed. The most common example of this is the loss of breast tissue from a mastectomy due to breast cancer. Implants are part of a reconstructive surgery process that works to restore the appearance of the lost tissue.

Company	Product	Phase	Indication
Mentor Corp	Low height contour profile moderate plus Memory Gel	PA	Implants
Mentor Corp	Tall Height Contour Profile Moderate Plus Gel	PA	
Mentor Corp	MemoryGel Breast Implant	A	
Mentor Corp	Lumera contoured gel-filled implants	M	
Mentor Corp	Moderate plus profile	M	
Mentor Corp	Saline-filled breast implant	M	
Mentor Corp	Spectrum breast implant	M	

Laboratory Kits and Assays

Laboratory kits and assays are research tools that assist in the discovery of cures for new diseases. Most research processes require the rapid replication of bacteria viruses or a patient's DNA or subsequent proteins. Research tools assist in that process.

Indication	Company	Product	Phase
Antibody Products	AnaSpec Inc	Anti-Bcl-xL	M
Clinical Kits and Assays	AnaSpec Inc	SensoLyte MMP-10	M
	Pharsight Corp	IVIVC Toolkit	M
Laboratory Kit and Assays	Guava Technologies Inc	Guava RapidQuant	M
	Ingenuity Systems	IPA-Tox	M
	AnaSpec Inc	AnaTagT Protein Labeling Kits	M
	Applied Biosystems Group	BigDye XTerminator Purification Kit	M
	Monogram Biosciences Inc	Replication Capacity (RC) HIV	M

Medical Devices

Medical devices are hybrid technologies combining inorganic components of a device with other technologies. Some devices are paired with an organic component intended to stimulate a biological response while others work with radio technology to allow for patients and medical professions to manipulate the device using controls outside the body.

Indication	Company	Product	Phase
Medical Device	Abbott Diabetes Care Inc	Copilot Healty Management System	A
	Abbott Diabetes Care Inc	Freestyle Lite Blood Glucose Monitoring System	A
	Abbott Vascular Inc	Starclose Hex-Hub Dilator	A
	Acclarent Inc	Microendoscope	A
	Acclarent Inc	Ethmoid Sinus Spacer	A
	Accuray Inc	Cyberknife Robotic Radiosurgery System	A
	Accuray Inc	Acumed Small Bone Locking System II	A
	Acumen Medical Inc	Acumen Insight Endocardial Visualization System	A
	Acumen Medical Inc	Acumen Lead Delivery Sheath With Stylet, Models Lds-10-64-Sty An	A
	Aesthera Corp	Aesthera Photopneumatic (Ppx) System	A
	Alara Inc	Crystalview T-Series Computed Radiography System, Models T110	A
	Allergan	Innamed® Silicone-Filled Breast Implants	A
	Allmed Systems Inc	Revolix Duo Laser System	A
	Alma Lasers Ltd	Accent	A
	Anatamage Inc	Invivodental	A
	Angioscore Inc	Angiosculpt® Scoring Balloon Catheter	A
	Aragon Surgical Inc	Aragon Surgical Lapcap	A
	Arthrocare Corp	Arthrocare Cavity Spinewand	A

Company	Product	Phase	Indication
Arthrocare Corp	Arthrocare Ent Plasma Wand	A	Medical Device
Arthrocare Corp	Arthrocare Spinewand	A	
Arthrocare Corp	Arthrocare System 12000	A	
Avantis Medical Systems Inc	Third Eye Retroscope Auxiliary Endoscopy System	A	
Bacchus Vascular Inc	Trellis-6 Peripheral Infusion System	A	
Bd Biosciences	Bd Tritest Cd3/Cd4/Cd45, Model 340383	A	
Benvenue Medical Inc	Benvenue Bone Tamp, Model Sa 0044	A	
Bioform Medical Inc	Radiesse Laryngeal Implant	A	
Boston Scientific Corp	Filterwire Ez Embolic Protection System	A	
Carbylan Biosurgery	Advacoat Sinus Gel And Stent	A	
Cardica Inc	Cardica C-Port Xa Distal Anastomosis System	A	
Cardica Inc	C-Port Flexa Distal Anastomosis System	A	
Cardica Inc	C-Port Distal Anastomosis System	A	
Cardima Inc	Revelation Helix	PA	
Cardim, Inc	REVELATION T-Flex	PA	
Cardiva Medical Inc	Boomerang Closurewire Vascular Closure System	A	
Cardiva Medical Inc	Boomerang Wire /Boomerang Plus Wire System, Model# B	A	
Carl Zeiss Meditec Inc	Cirrus Hd-Oct, Model 4000	A	
Carl Zeiss Meditec Inc	Horus Laser Keratome	A	
Cepheid	Xpert Ev, Model Gxev-100n-10; Genexpert Dx System, Models P/N 90	A	
Cepheid	Xpert Mrsa	A	
Cerus Corp	Intercept Blood System for Plasma	III	
Cerus Corp	Intercept Blood System for Platelets	III	
Conceptus Inc	Essure	A	
Conformis Inc	Conformis Metal Backed Tibial Component("Mbt")	A	
Cormatrix Cardiovascular Inc	Cormatrix Patch For Cardiac Tissue Repair	A	
Dade Behring Inc	Microscan Microstrep Plus Panel Cefepime	A	
Dade Behring Inc	Microscan Microstrep Plus Panel Erythromycin	A	
Dade Behring, Inc.	Microscan Microstrep Plus Panel- Clarithromycin	A	
Dade Behring Inc	Microscan Synergies Plus Gram Positive Mic/Combo Panels	A	
Dfine Inc	Space 360 Delivery System	A	
Diamics Inc	Diamics Cercol Cervical Sample Collector System	A	
Dolomite Biotech Sdn Bhd	Ssafe Plus Disposable Safety Syringe, 3 Cc And 5 Cc	A	
Dyansys Corp	Portable Ecscope	A	

Indication	Company	Product	Phase
Medical Device	Endotex Interventional Systems Inc	Endotex® Nexstent® Carotid Stent And Delivery System And Endotex® Carotid Stent And Monorail® Delivery System	A
	Flowcardia Inc	The Crosser Catheter, Model Cr1100 And System Electronics	A
	Foxhollow Technologies Inc	SilverHawk SXL	M
	Foxhollow Technologies Inc	Silverhawk Peripheral Plaque Excision System	A
	Gynesonics Inc	Gynesonics Ec6 Transducer	A
	Hansen Medical Inc	Hansen Medical Catheter Control System	A
	Hayes Medical Inc	36mm Cocr Femoral Head And 36mm Acetabular Insert	A
	Hayes Medical Inc	Unisyn Ha Plasma Modular Hip	A
	Hoya Conbio Inc	Diodent Micro Dental Laser System, Models 810 And 980	A
	Iridex Corp	Iridex Wireless Footswitch	A
	Iridex Corp	Iridex Oculight Tx	A
	Jms North America Corp	Jms Planecta Stopcock	A
	Juniper Medical Inc	Juniper Cooling Device Xtra	A
	Kerberos Proximal Solutions Inc	Rinspiration Catheter System, Models 50135, 550135, P7065, P7013	A
	Kyphon Inc	Discyphor Catheter System, Model D01a	A
	Lasering SRL	Velure Family Of Diode Lasers And Delivery Device Accessories	A
	Lemaitre Vascular Inc	Flexcel Carotid Shunt (Inlying), Model 2020-05	A
	Lin-Zhi International Inc	Lzi Amphetamine-Specific Oral Fluid Homogeneous Enzyme Immunoassay	A
	Lin-Zhi International Inc	Methamphetamine Oral Fluid Homogeneous Enzyme Immunoassay	A
	Mentor Corp	Mentor Memorygel™ Silicone Gel-Filled Breast Implants	A
	Mentor Corp	Contour profile becker 35 expander / implant	M
	Mentor Corp	Contour profile Tissue Expander	M
	Mercator Medsystems Inc	Mercator Microsyringe Ii Infusion Catheter	A
	Micrus Endovascular Corp	ENZO Steerable Microcatheter	A
	Micrus Endovascular Corp	Micrus Microcoil Delivery System	A
	Micrus Endovascular Corp	Micrus Courier Enzo Microcatheter 0.017	A
	Micrus Endovascular Corp	Micrus Microcoil System	A
	Micrus Endovascular Corp	Micrus Microcoil System, "Cashmere" Model Src	A
	Nellcor Puritan Bennett Inc	Duramax Reusable Oximetry Sensor	A
	Neoguide Systems Inc	Neoguide Endoscopy System	A
	Neotract Inc	Neotract Anchor	A
	New Star Lasers Inc	Cooltouch, Model Ctev	A
	Nobel Biocare Ab	Nobelactive Internal Connection Implant	A
	Optovue Inc	Rtvue	A

Company	Product	Phase	Indication
Ostial Solutions LLC	Ostial Pro Stent Positioning System	A	Medical Device
Parnell Pharmaceuticals Inc	Mouthkote Oral Moisturizer, Model 50930-098	A	
Penumbra Inc	Neuron Support Catheter System, Model 5f/6f	A	
Percutaneous Systems Inc	Cystoglide Introducer Sheath	A	
Percutaneous Systems Inc	Expressway Intermittent Catheter	A	
Prosurg Inc	Cranioclamp Bioabsorbable Cranial Bone Flap Fixation System	A	
Prosurg Inc	Xsorb Bioabsorbable Craniofacial Bone Fixation System & Accessor	A	
Radiant Medical	Reprieve Endovascular Temperature Therapy System	A	
Bioform Medical, Inc.	Radiesse	A	
Regulatory Management Services	Interson Usb Ultrasound Probe System	A	
Reliant Technologies Inc	Fralex Sr 1500 Laser System	A	
Reliant Technologies Inc	Fraxel Ii Sr Laser System	A	
Reliant Technologies Inc	Fraxel Iii Sr Laser System And Accessories	A	
Rfa Medical Inc	Incircle Bi-Polar Rf Ablation System	A	
Rita Medical Systems Inc	Habib 4x Laparoscopic	A	
Rita Medical Systems Inc	Uniblatch Electrosurgical Device	A	
Rubicor Medical Inc	Rubicor Magic Breast Biopsy Device, Model 31537	A	
Rubicor Medical Inc	Flexible Loop Electrosurgical Electrode	A	
Sanarus Medical Inc	V2 Treatment System	A	
Sciton Inc	Profile Multi-Platform System	A	
Spectrum International	Prometey, Model G1-03	A	
Starion Instruments	Starion Instruments Thermal Litigating Shears	A	
Stellartech Research Corp	Stellartech 100 Coagulation System	A	
Stryker Endoscopy	Stryker Peek Zip Suture Anchor	A	
Surgrx Inc	Enseal Ptc Trio	A	
Surgrx Inc	Enseal Ptc Tissue Sealing Device	A	
Surgrx Inc	Enseal Ptc Tissue Seating Sealing Device	A	
Thermage Inc	Thermage Thermacool System	A	
Thermage Inc	Thermassage	A	
Thermogenesis Corp	Cryoseal Fs Applicator System	A	
Varian Medical Systems Inc	High-Definition 120 Multileaf Collimator (Hd120 Mlc)	A	
Varian Medical Systems Inc	Rpm Respiratory Gating System	A	
Varian Medical Systems Inc	Trilogy Radiotherapy Delivery System And Trilogy Tx Delivery Sys	A	
Varian Medical Systems Inc	Varian Esophagus Bougie Applicator	A	
Vascular Solutions Inc	Optical Guidance Platform	A	
Volcano Corp	SpiderFX Embolic Protection Device	M	
Volcano Corp	Smartwire Pressure Guide Wire, Model 66xx	A	
Volcano Corp	Visions Pv 8.2 Intravascular Ultrasound Imaging Catheter	A	