



# Clinical Devices and 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 whether infection is present 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.

### Accessories

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

	COMPANY	PRODUCT	PHASE
Accessories	Cardima, Inc.	TX Select	PA
	Cardima, Inc.	EP Select	M
	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.

	COMPANY	PRODUCT	PHASE
Adjunct	CV Therapeutics, Inc.	Regadenoson / CVT-3146	III
	Novartis AG	HCV c200	M

### Clinical Device

Clinical devices are a class of medical devices designed for self administration. The course and term of treatment for many therapies often requires dosing outside a trained medical professional environment. Clinical devices give patients the ability to administer their own medication in a safe and convenient manner.

	COMPANY	PRODUCT	PHASE
Clinical Device	Genentech, Inc.	Nutropin AQ Pen	M

### 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.

	COMPANY	PRODUCT	PHASE
Clinical Systems	Cerus Corporation	INTERCEPT Blood System for Plasma	III
	Cerus Corporation	INTERCEPT Blood System for Platelets	III
	Nuvelo, Inc. New	NuCleave Genotyping and Haplotyping Platform	M

### Clinical Test

Clinical testing allows for the study and examination of an individual, disease or virus on the genetic level. Through genetic genotyping and phenotyping, researchers are able to use specific genetic information to assess risks to tissue damage, consider responsiveness to different treatments, and evaluate drug resistance.

COMPANY	PRODUCT	PHASE	Clinical Test
Novartis AG	Procleix Ultrio Assay	PA	
Novartis AG	Procleix West Nile Virus Assau	A	
XDx	AlloMap molecular expression testing	M	
Novartis AG	Anti HBS Eci	M	
Novartis AG	Anti HCV Eci	M	
Novartis AG	Chiron Riba HCV 3.0 Strip Immunoblot	M	
Adeza Biomedical Corp.	E-tegrity Test	M	
Monogram Biosciences, Inc.	GeneSeq HBV	M	
Monogram Biosciences, Inc.	GeneSeq HIV	M	
Novartis AG	HBCore Elisa	M	
Novartis AG	HBsAg Eci	M	
Novartis AG	HBzAg system 2 Elisa	M	
Novartis AG	HBsAg system 3 Elisa	M	
Novartis AG	HCV 3.0 Elisa	M	
Novartis AG	HCV c22-3	M	
Novartis AG	HCV c100-3	M	
Novartis AG	HCV HC34	M	
Novartis AG	HCV NS5	M	
Novartis AG	HIV-1/2 Elisa	M	
Novartis AG	HIV-1/HCV NAT Blood Screening	M	
Monogram Biosciences, Inc.	PhenoSense GT	M	
Monogram Biosciences, Inc.	PhenoSense HIV	M	
Monogram Biosciences, Inc.	PhenoSense HIV Entry	M	
Novartis AG	RIBAHCV 3.0 SIA	M	
Novartis AG	Tubergen Test/Tuberkulin	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 often work by detecting changes in chemical concentrations or identifying and illuminating organs to enhance study by outside diagnostics tools (such as MRI machines). The information these tests and procedures yield, provides patients and healthcare providers specific information about the status of diseases or disorders.

	COMPANY	PRODUCT	PHASE
Diagnostics	<b>Berlex</b>	Magnevist (gadopentetate dimeglumine)	II
	<b>Pharmacyclics, Inc.</b>	Gadolite/Citra Vu	PA
	<b>Cholestech Corporation</b>	L D X System (TC)	PA
	<b>Bayer AG</b>	AC1 Now Monitor	M
	<b>Novartis AG</b>	Biocine Test - PPD	M
	<b>Mentor Corporation</b>	BTA stat test	M
	<b>Cholestech Corporation</b>	Cholestech GDx System	M
	<b>Nektar Therapeutics</b>	Definity (perflutren lipid microsphere)	M
	<b>Pharmagenesis, Inc.</b>	Feridex / ferumoxides	M
	<b>Berlex</b>	Feridex I.V. (ferumoxides)	M
	<b>Adeza Biomedical Corp.</b>	FullTerm	M
	<b>Novartis AG</b>	HCV Ag ELISA 2.0	M
	<b>Cholestech Corporation</b>	The L-D-X Analyzer	M
	<b>Cholestech Corporation</b>	L D X System (Alanine Aminotransferase (ALT))	M
	<b>Cholestech Corporation</b>	L D X System (Bun and Creatinine)	M
	<b>Cholestech Corporation</b>	L D X System (Lipid Profile)	M
	<b>Cholestech Corporation</b>	L D X System (TC and Glucose Panel)	M
	<b>Cholestech Corporation</b>	L D X System (TC and HDL Panel)	M
	<b>Cholestech Corporation</b>	L D X System (TC, HDL and Glucose Panel)	M
	<b>Berlex</b>	Magnevist Injection (gadopentetate dimeglumine)	M
	<b>InSite Vision Incorporated</b>	OcuGene / Glaucoma Genetics Test	M
	<b>Genomic Health, Inc.</b>	Oncotype DX	M
	<b>Cardima, Inc.</b>	Pathfinder	M
	<b>Cardima, Inc.</b>	Pathfinder Mini	M
	<b>Novartis AG</b>	Procleix HIV-1/HCV Assay	M
	<b>Cardima, Inc.</b>	Tracer	M
<b>Berlex</b>	Ultravist (iopromide)	M	

### Drug Delivery

As therapeutic treatments grow more complex and time specific, drug delivery innovations play a key role in managing a course of treatment. Many drug delivery innovations occur on the chemical level allowing for timed release of multiple therapies if needed.

COMPANY	PRODUCT	PHASE	
<b>Aradigm Corp.</b>	AERx Pulmonary Drug Delivery System	M	<b>Technology</b>
<b>Impax Laboratories, Inc.</b>	Concentric Multiple-particulate Delivery System (CMDS)	M	<b>Drug Delivery</b>
<b>Impax Laboratories, Inc.</b>	Dividable Multiple-action Delivery System (DMDS)	M	
<b>Valentis, Inc.</b>	DNA Vaccine Platform	M	<b>Technology</b>
<b>InSite Vision Incorporated</b>	DuraSite	M	<b>Drug Delivery</b>
<b>Valentis, Inc.</b>	Gene Medicine Platform	M	<b>Technology</b>
<b>Valentis, Inc.</b>	GeneSwitch System	M	
<b>Nektar Therapeutics</b>	Inhance (Pulmonary Delivery System)	M	<b>Drug Delivery</b>
<b>Impax Laboratories, Inc.</b>	Multi-Ingredient Multiple-Action Delivery System (MMDS)	M	
<b>Impax Laboratories, Inc.</b>	Particle Dispersion Systems (PDS)	M	
<b>Impax Laboratories, Inc.</b>	Pharmaceutical Stabilization System (PSS)	M	
<b>Impax Laboratories, Inc.</b>	Programmed Multiple-action Delivery System (PMDS)	M	
<b>Impax Laboratories, Inc.</b>	Rapid Dissolving Delivery System (RDDS)	M	
<b>Impax Laboratories, Inc.</b>	Sustained Release Liquid Delivery System (SLDS)	M	
<b>Impax Laboratories, Inc.</b>	Timed Multiple-action Delivery System (TMDS)	M	
<b>Sangamo BioSciences, Inc.</b>	Universal Gene Recognition Technology	M	<b>Technology</b>
<b>Novartis Ag</b>	Vitrasert Implant	M	<b>Drug Delivery</b>
<b>Sangamo BioSciences, Inc.</b>	Zinc Finger DNA binding protein (ZFP) Technology	M	<b>Technology</b>

### Drug Screening

Drug screening technologies assess the effectiveness a drug will have on a patient. Drug screening results help identify appropriate treatments and doses.

COMPANY	PRODUCT	PHASE	
<b>Monogram Biosciences, Inc.</b>	Arteas (Oasis)	M	<b>Drug Screening</b>
<b>Monogram Biosciences, Inc.</b>	PhenoScreen	M	

### Genomics

Genomic technology plays an important role in emerging research. Genomic technology allows for a more efficient study of gene and protein expression. This information will provide better insights into the pathology of a variety of disorders allowing for the development of cures in the future.

	COMPANY	PRODUCT	PHASE
Genomics	Monogram Biosciences, Inc.	ACLARA's eTag assay System	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
Implants	Mentor Corporation	Low height contour profile moderate plus Memory Gel	PA
	Mentor Corporation	Memory Gel	PA
	Mentor Corporation	Tall height contour profile moderate Plus gel	PA
	Mentor Corporation	Lumera contoured gel-filled implants	M
	Mentor Corporation	Moderate plus profile	M
	Mentor Corporation	Saline-filled breast implant	M
	Mentor Corporation	Saline-filled testicular prostheses	M
	Mentor Corporation	Silicone gel 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 patients DNA or subsequent proteins. Research tools assist in that process.

	COMPANY	PRODUCT	PHASE
Clinical Kits and Assays	Novartis AG	HBCore	M
Laboratory Kits and Assays	Monogram Biosciences, Inc.	Replication Capacity (RC) HIV	M
Clinical Kits and Assays	Novartis AG	RIBA HIV-1/HIV-2 SIA	M

### Medical Device

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.

COMPANY	PRODUCT	PHASE	
Cardima, Inc.	Navablator	PA	Medical Device
Cardima, Inc.	Revelation Tx	PA	
Cardima, Inc.	Revelation T-Flex	PA	
VIVUS, Inc.	Actis	M	
Cardima, Inc.	Cardima Ablation System	M	
Mentor Corporation	Contour profile becker 35 expander / implant	M	
Conceptus, Inc.	Essure (STOP)	M	
Cardima, Inc.	Revelation	M	
Curon Medical, Inc.	Secca System	M	
Mentor Corporation	Self-Cath intermittent catheter	M	
Mentor Corporation	SpiroFlo	M	
Curon Medical, Inc.	Stretta System	M	

### Surgery

Surgery often is a complex invasive procedure, exposing the body and internal organs to disease, and complications. Surgical therapeutics work in pre- or post-operative situations to prevent complications and manage pain.

COMPANY	PRODUCT	PHASE	
Nektar Therapeutics	SprayGel	III	Surgery

### Surgical Sealant

Surgical sealants are used during a surgical procedure to assist in closing up wounds.

COMPANY	PRODUCT	PHASE	
Nektar Therapeutics	DuraSeal	M	Surgical Sealant

