

Overview

Breakthrough developments in the Medical Device (MedTech) sector present significant investment opportunities for investors who understand what catalyst events to monitor. Filing a **PMA (Premarket Approval)** application with the FDA is one of the most important catalyst events for any MedTech company, much like the filing of an **NDA (New Drug Application)** for a drug company.

In order to file a PMA with the FDA, the device needs to be classified as a Class III Medical Device. These devices are generally high value and technologically driven products that require extensive clinical trials and are protected by patents. Heart valves, pacemakers, silicone breast implants, hip and knee replacement systems and drug-eluting stents are examples of the better known Class III Medical Devices.

This report takes advantage of Revere's proprietary classification system and comprehensive company coverage to identify Medical Device companies with **PMAs pending FDA approval**. Key company-specific information includes:

- **Device tradenames and indications**
- **Estimated approval dates**
- **Competitive landscape of the products**
- **Potential market size of the products**
- **Approval impact ranking**

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Notes:

- a) Approval timeframes are Revere estimates based on historic average time to approval for Premarket Approval (PMA) applications.
- b) Devices developed by private firms or companies not traded publicly in the U.S. are excluded from this analysis.

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1. Companies with Current PMA Filings


















2006	2007	Uncertain Pending Discussion with FDA
Abbott Laboratories (ABT)	Allergan, Inc. (AGN) [2]	EP MedSystems, Inc. (EPMD)
Allergan, Inc. (AGN)	Angiotech Pharmaceuticals, Inc. (ANPI)	Ortec International Inc. (ORTN)
Anika Therapeutics, Inc. (ANIK)	BSD Medical, Inc. (BSM)	
Digene Corporation (DIGE)	Boston Scientific Corp (BSX)	
ev3 Inc. (EVVV)	Medtronic, Inc. (MDT) [2]	
Johnson & Johnson (JNJ)	Mentor Corporation (MNT) [2]	
Medtronic, Inc. (MDT)	Uroplasty, Inc. (UPI)	
Possis Medical, Inc. (POSS) [2]		
Stryker Corporation (SYK)		
St. Jude Medical, Inc. (STJ)		
STAAR Surgical Company		
ThermoGenesis Corp. (KOOL)		
TriPath Imaging, Inc. (TPTH)		
Wright Medical Group (WMGI)		
Total Companies = 14	Total Companies = 7	Total Companies = 2

- Notes:**
1. Companies with more than one PMA are shown in **bold type** with the number of PMA in brackets [].
 2. Some PMA are jointly owned by more than one company through licensing agreements.
 3. Click the company name to view PMA Filed devices for the company in [Revere Research](#).

Based on Revere's estimate, there are currently 246 publicly traded Medical Device companies in the U.S. As can be seen from the above table, only 21 out of the 246 have active PMAs under FDA review. This telling statistic conveys 3 important pieces of insights:

- **Innovative, ground breaking product developments take place only in a small % of Medical Device companies**
- **Discovering great Medical Device investment opportunities requires identifying those that have maintained a successful track record of filing PMAs and gaining FDA approvals**
- **Small to Mid-cap Medical Device companies who are able to pass all the clinical and regulatory hurdles involved in filing PMAs have the greatest potential for explosive growth**

2. PMA Filings by Sector*

2006	2007	Uncertain Pending Discussion with the FDA
I *Healthcare  Medical Devices [14]  Cardiology [3]  Clinical Diagnostics [2]  General Surgery [1]  Ophthalmology [1]  Orthopedics [3]  Plastic/Reconstructive [2]  Vascular [2]	I *Healthcare  Medical Devices [9]  Cardiology [2]  Oncology [1]  Plastic/Reconstructive [4]  Urology [1]  Vascular [1]	I *Healthcare  Medical Devices [2]  Cardiology [1]  Plastic/Reconstructive [1]
Total Estimated Approvals = 14	Total Estimated Approvals = 9	Total Estimated Approvals = 2

*Based on Revere's [proprietary classification system](#).

Revere classifies the Medical Device sector into 21 sub-sectors, with each facing a different set of market opportunities, product innovations and life cycle, and competitive dynamics. Success in Medical Device investment, therefore, hinges greatly on identifying companies with the following shared characteristics: participation in sub-sectors with growing market opportunities, breakthrough innovations, and moderate competitive intensity.

In this report, 26 PMA filings have been identified and analyzed, with Cardiology/Vascular, Plastic/Reconstructive, and Orthopedic each accounting for 9, 7, and 3 PMA filings respectively. Simply put, the greater the number of PMA filings a sub-sector has, the more likely it is a rapidly growing market with a healthy pipeline of breakthrough products. While competition is intense on the surface for all 3 sub-sectors, the true gauge of competitive intensity depends on the actual product being developed, which is detailed in the next section.

3. Estimated PMA Approvals in 2006

Company (Symbol)	Class III Device Candidate	Indication	Estimated Approval Date*	*Device Will Compete with Three or Fewer Similar Devices if Approved?	1 st or 2nd Class III Approved Device of the Company?	Estimated Market Size (M=Million, B=Billion)
St. Jude Medical, Inc. (STJ)	Proxis Embolic Protection System	Embolism Protection During Percutaneous Coronary Intervention (PCI) Procedures	May 2006 (company disclosure)	No—Multiple	No	300M-500M
Wright Medical Group (WMGI)	CONSERVE Plus Hip Resurfacing Implant	Hip Joint Replacement	July 2006 (Revere estimate)	Yes—Cormet System (SYK), Birmingham Hip Resurfacing System (SNN)	No	300M-550M
Possis Medical, Inc. (POSS)	AngioJet Ultra Console	Thrombus (Blood Clot) Removal from Arteries and Veins	July 2006 (company disclosure)	No—Multiple	No	200M-300M
	AngioJet SpiroFlex Catheter	Thrombus (Blood Clot) Removal from Arteries and Veins	October 2006 (Revere estimate)	No—Multiple	No	200M-300M
Abbott Laboratories (ABT)	FreeStyle Navigator Continuous Glucose Monitoring System	Continuous Glucose Monitoring	3Q:2006 (Revere estimate)	No—Multiple	No	1B-3B
STAAR Surgical Company (STAA)	Visian TICL	Myopia (Nearsightedness) and Astigmatism	October 2006 (Revere estimate)	Yes—Only Device Available for this Indication	No	4B-5B
Anika Therapeutics, Inc. (ANIK)	REDEFYNE	Hyaluronic Acid for Dermal Defects (Fine Lines, Folds, Scars)	November 2006 (Revere estimate)	No—Multiple	No	400M-500M
Johnson & Johnson (JNJ)	Cordis Precise Self-Expanding Stent	Carotid Artery Disease Restenosis Prevention	November 2006 (Revere Estimate)	No—Multiple	No	200M-250M
Allergan, Inc. (AGN)	Round Silicone Gel-Filled Breast Implants	Silicone Breast Implants	December 2006 (company disclosure)	Yes—MemoryGel, Contour Profile (MNT)	No	350M-400M

ev3 Inc. (EVVV)	Protégé Stent/ SpideRX	Carotid Artery Disease Restenosis Prevention	December 2006 (company disclosure)	No—Multiple	No	200M-250M
Medtronic, Inc (MDT)	AMPLIFY rhBMP-2 Matrix	Spinal Bone Growth Stimulation for the Treatment of Degenerative Disc Disease	<i>December 2006 (Revere estimate)</i>	Yes— INFUSE rhBMP Matrix (MDT). INFUSE is use for anterior fusion, while AMPLIFY is intended for posterior fusion.	No	500M-700M
Stryker Corporation (SYK)	Cornet Hip Resurfacing System	Hip Joint Replacement	December 2006 (company disclosure)	Yes—Birmingham Hip Resurfacing System (SNN), Conserve Plus Resurfacing Implant (WMGI)	No	300M-550M
ThermoGenesis Corp. (KOOL)	CryoSeal Fibrin Sealant (FS) System	Autologous Fibrin Hemostatic Sealant Production and Delivery	December 2006 (company disclosure)	No—Multiple	Yes	450M-500M
Digene Corporation (DIGE) / TriPath Imaging Corp. (TPTH)	SurePath	PAP Smear Collection System for Cervical Cancer Screening	1H:06 (company disclosure)	Yes—Only Device Available for this Indication	No	600M-800M

* Dates in **bold** indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases. Dates in *italics* indicate Revere estimates based on PMA (Premarket Approval) submission dates.

4. Estimated PMA Approvals in 2007

Company (Symbol)	Class III Device Candidate	Indication	Estimated Approval Date*	Device Will Compete with Three or Fewer Similar Devices if Approved?	1st or 2nd Class III Approved Device of the Company?	Estimated Market Size (M=Million, B=Billions)
Medtronic, Inc (MDT)	Talent Thoracic Stent	Thoracic Aneurysm (TA)	<i>January 2007</i> (Revere estimate)	Yes—Only Device Available for this Indication	No	250M-350M
	Endeavor Drug Eluting Coronary Stent System	Restenosis Prevention/Coronary Artery Disease	2007 (company disclosure)	Yes— Cordis CYPHER (JNJ/GDT), TAXUS Liberte (BSX/ANPI)	No	4B-5B
Allergan, Inc. (AGN)	Inamed Juvederm	Dermal Filler for Wrinkle Removal and Other Skin Augmentation	<i>February 2007</i> (Revere estimate)	Yes—Restylane (MRX), REDEFYNE (ANIK)	No	450M-500M
	Bio-Dimensional Cohesive Gel Matrix	Silicone Breast Implants	May 2007 (company disclosure)	Yes—MemoryGel, Contour Profile (MNT)	No	350M-400M
Boston Scientific Corp (BSX) / Angiotech Pharmaceuticals, Inc. (ANPI)	TAXUS Liberte (Paclitaxel-Eluting Coronary Stent)	Restenosis Prevention/Coronary Artery Disease	<i>May 2007</i> (Revere estimate)	Yes—Cordis CYPHER Sirolimus Eluting Stent (JNJ/GDT), Endeavor Drug-Eluting Coronary Stent (MDT)	No	4B-5B
BSD Medical Corporation (BSM)	BSD-2000 Cancer Treatment System	Thermotherapy Treatment of Cancer Tumors Deep within the Body Tissue	<i>May 2007</i> (Revere estimate)	Yes—Microfocus APA 1000 (CLN)	Yes	1B-2B
Mentor Corporation (MNT)	MemoryGel Silicone Gel Breast Implant	Silicone Breast Implants	<i>Early 2007</i> (Revere Estimate)	Yes—Bio-Dimensional Cohesive Gel Matrix, Round Silicone Gel-Filled Breast Implant (AGN)	No	350M-400M
	Contour Profile Gel (CPG) Breast Implants	Silicone Breast Implants	<i>2007</i> (Revere Estimate)	Yes—Bio-Dimensional Cohesive Gel Matrix, Round Silicone Gel-Filled Breast Implant (AGN)	No	350M-400M
Uroplasty, Inc. (UPI)	Macroplastique Implantation System	Tissue Bulking Agent for Female Urinary Incontinence	Late 2007 (company disclosure)	Yes—Durasphere EXP (BSX), Contigen (BCR)	Yes	100M-200M

* Dates in **bold** indicate that Revere has confirmed directly with the company or indirectly through company filings and press releases. Dates in *italics* indicate Revere estimates based on PMA (Pre-market Approval) submission dates.

5. Uncertain PMA Approvals Pending FDA Discussion

Company (Symbol)	Class III Device Candidate	Indication	Estimated Approval Date*	Device Will Compete with Three or Fewer Similar Devices if Approved?	1st or 2nd Class III Approved Device of the Company?	Estimated Market Size (M=Million, B=Billion)
EP MedSystems, Inc. (EPMD)	ALERT CS/RA Catheter System	Rate Adaptive Catheter System for the Treatment of Atrial Fibrillation	Approval timeline uncertain depending on submission of additional data	No—Multiple	Yes	1B-2B
Ortec International Inc. (ORTN)	OrCel	Bilayered Cellular Matrix for Venous Leg Ulcer Treatment	Approval timeline uncertain depending on submission of additional data	Yes—Apligraf (NVS)	Yes	150M-200M

6. Approval Impact Ranking

While knowing the estimated market size provides a good framework for analyzing the individual device's revenue potential, it does not address the likely impact to the company's stock price if its PMA is approved. The following table calculates an Estimated Market Size/Market Cap. Ratio for each company and rank them in decreasing order. This ratio is meant to approximate the impact of a PMA approval to the company's stock price—larger ratios indicate a greater likelihood of significant price movements.

Company (Symbol)	Class III Device Candidate	Market Cap. (M)*	Est. Market Size (M=Million, B=Billion)	Estimate Market Size / Market Cap. Ratio
EP MedSystems, Inc. (EPMD)	ALERT CS/RA Catheter System	70	1B-2B	14-29
STAAR Surgical Company (STAA)	Visian TICL	224	4B-5B	18-22
Ortec International Inc. (ORTN)	OrCel	13	150M-200M	12-15
BSD Medical Corporation (BSM)	BSD-2000 Cancer Treatment System	125	1B-2B	8-16
Uroplasty, Inc. (UPI)	Macroplastique Implantation System	14	100M-200M	7-14
Anika Therapeutics, Inc. (ANIK)	REDEFYNE	121	400M-500M	3-4
Angiotech Pharmaceuticals, Inc. (ANPI)	TAXUS Liberte (Paclitaxel-Eluting Coronary Stent)	1,239	4B-5B	3-4
TriPath Imaging Corp. (TPTH)	SurePath	295	600M-800M	2-3

ThermoGenesis Corp. (KOOL)	CryoSeal Fibrin Sealant (FS) System	223	450M-500M	2.0-2.2
Possis Medical, Inc. (POSS)	AngioJet Ultra Console/AngioJet SpiroFlex Catheter	169	200M-300M	1-2
Digene Corporation (DIGE)	SurePath	957	600M-800M	0.6-0.8
Wright Medical Group (WMGI)	CONSERVE Plus Hip Resurfacing Implant	784	300M-550M	0.4-0.7
ev3 Inc. (EVVV)	Protégé Stent/SpideRX	835	200M-250M	0.2-0.3
Mentor Corporation (MNT)	MemoryGel Silicone Gel Breast Implant/Contour Profile Gel (CPG) Breast Implants	1909	350M-400M	0.20-0.21
Boston Scientific Corp (BSX)	TAXUS Liberte (Paclitaxel-Eluting Coronary Stent)	32,098	4B-5B	0.12-0.16
Medtronic, Inc (MDT)	Endeavor Drug Eluting Coronary Stent System	57,997	4B-5B	0.07-0.09
	AMPLIFY rhBMP-2 Matrix		500M-700M	0.008-0.01
	Talent Thoracic Stent		250M-350M	0.004-0.006
Abbott Laboratories (ABT)	FreeStyle Navigator Continuous Glucose Monitoring System	64,818	2B-3B	0.03-0.05
Allergan, Inc. (AGN)	Inamed Juvederm	12970	450M-500M	0.03-0.04
	Bio-Dimensional Cohesive Gel Matrix		350M-400M	0.026-0.031
St. Jude Medical, Inc. (STJ)	Proxis Embolic Protection System	14,364	300M-500M	0.02-0.03
Stryker Corporation (SYK)	Cormet Hip Resurfacing System	17,801	300M-550M	0.02-0.03
Johnson & Johnson (JNJ)	Cordis Precise Self-Expanding Stent	174,725	200M-225M	0.0010-0.0013

*Market Cap. based on closing stock price on 5/8/2006.

7. Price and Financial Info

Data as of May 9, 2006

Company (Symbol)	Last Price	Market Cap. (M)	30-Day Avg. Volume	1-Year Return	Relative Performance vs. Revere Med. Devices Index	Estimated Market Size / Market Cap. Ratio	*Average Analyst Rating / # of Analyst Coverage	Options Available?
Abbott Laboratories (ABT)	42.25	64,483	4,482,780	-13.90%	-29.41%	0.03-0.05	1.92 / 15	YES
Allergan, Inc. (AGN)	96.45	12,892	1,500,124	29.60%	14.09%	0.06-0.07	2.22 / 4	YES
Angiotech Pharmaceuticals, Inc. (ANPI)	14.82	1,249	427,844	1.16%	-14.35%	3-4	1.18 / 7	YES
Anika Therapeutics, Inc. (ANIK)	11.21	118	84,672	-33.67%	-49.18%	3-4	3 / 1	NO
Boston Scientific Corp. (BSX)	21.36	31,264	16,600,360	-27.59%	-43.10%	0.12-0.16	1.6 / 18	YES
BSD Medical Corporation (BSM)	5.95	123	90,152	109.51%	94.00%	8-16	N/A	YES
Digene Corporation (DIGE)	39.96	901	279,267	63.90%	48.39%	0.6-0.8	1.67 / 7	YES
EP MedSystems, Inc. (EPMD)	2.30	70	36,491	-24.59%	-40.10%	14-29	2 / 1	NO
ev3 Inc. (EVVV)	14.93	843	414,431	N/A	N/A	0.2-0.3	2 / 5	YES
Johnson & Johnson (JNJ)	58.36	173,683	8,537,468	-14.39%	-29.90%	0.0010-0.0013	2 / 17	YES
Medtronic, Inc. (MDT)	48.35	58,359	13,849,448	-7.18%	-22.69%	0.082-0.11	1.8 / 26	YES
Mentor Corporation (MNT)	42.96	1,889	285,268	12.96%	-2.55%	0.20-0.21	1.75 / 7	YES
Ortec International Inc. (ORTN)	0.27	23	143,086	-44.90%	-60.41%	12-15	N/A	NO
Possis Medical, Inc. (POSS)	9.77	168	53,326	7.96%	-7.56%	1-2	2 / 1	YES
STAAR Surgical Company (STAA)	8.90	222	125,717	131.17%	115.66%	18-22	2 / 1	YES
St. Jude Medical, Inc. (STJ)	38.60	14,246	5,258,616	1.21%	-14.31%	0.02-0.03	2.26 / 22	YES
Stryker Corporation (SYK)	44.05	17,890	1,787,032	-8.63%	-24.14%	0.02-0.03	2.24 / 20	YES
ThermoGenesis Corp. (KOOL)	4.15	227	183,432	11.56%	-3.95%	2-2.2	1 / 1	NO
TriPath Imaging, Inc. (TPTH)	7.66	294	164,032	-1.54%	-17.05%	2-3	2.33 / 3	NO
Uroplasty, Inc. (UPI)	2.05	14	7,668	-56.48%	-71.99%	7-14	N/A	NO
Wright Medical Group (WMGI)	22.02	753	407,673	-13.58%	-29.09%	0.4-0.7	2.36 / 13	YES

*Average Analyst Rating range from 1 to 5, with 1=Strong Buy, 2=Buy, 3=Hold, 4=Sell, 5=Strong Sell

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