



# Post-Approval Studies Update

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Circulatory Devices Panel Meeting

November 29, 2007

# Outline

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- Recent developments in the CDRH Post-Approval Studies (PAS) Program
- Cardiovascular PAS Update

# Areas of PAS Program Transformation

- Oversight
- Tracking
- Review
- Guidance
- Web Posting
- Postmarket Advisory Panel Updates
- Building Public Health Partnerships

# PAS Oversight

January 1, 2005 Initial Transfer

April 2, 2007 Full Transfer

ODE/OIVD



OSB

# PAS Tracking System

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- Developed & instituted automated tracking system for post-approval study commitments

# Premarket Review Process

- Epidemiologist on each PMA team
  - Lead the design of PAS study
  - Work interactively with sponsors
  - Present at Panel meetings
- PAS Protocol/outline finalized at the time of PMA approval
- Agreed upon study timelines

# Postmarket Review Process

- Epidemiology lead on all PAS Reports and all PAS Supplements involving changes to PAS protocol
- Postmarket Review Team
  - Feedback to premarket

# Post-Approval Studies Guidance Document

- Guidance for Industry and FDA Staff:  
Procedures for Handling Post-Approval  
Studies Imposed by PMA Order  
(December 21, 2006, revised August 1,  
2007)

<http://www.fda.gov/cdrh/osb/guidance/1561.html>

# PAS Web Page

- Went live on April 6, 2007
- Reporting Schedule Status
- PAS Study Progress
- Post – 2005 Studies

[http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma\\_pas.cfm](http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pma_pas.cfm)

# Reporting Status Definitions

- Report On- time : FDA has received the scheduled Interim or Final Post-Approval Study Status Report by the due date.
- Report Overdue : FDA has not received the Interim or Final Post-Approval Study Status Report by the due date.
- Report Overdue/Received: FDA has received the Interim or Final Post-Approval Study Status Report, although past the due date.
- Final Post-Approval Study Report Submitted : The study has been concluded or terminated, and the Final Post-Approval Study Report has been submitted.

# Study Status Definitions

- Protocol Pending: FDA has not approved the study protocol and it has been less than 6 months since the approval of the PMA.
- Protocol Overdue: FDA has not approved the study protocol and it has been 6 months or more since the approval of the PMA
- Study Pending : The protocol has been approved but the study has not begun (i.e., no subjects have been enrolled), and the projected date for completing patient accrual has not passed.
- Study On-time : The study is proceeding according to, or is ahead of, the agreed upon schedule .
- Study Overdue: The study has not been initiated by the projected date for completion of patient enrollment or the study is behind the agreed upon schedule.
- Study Terminated : FDA granted an early termination of the study because the study is either no longer feasible or would no longer provide useful information.
- Study Completed: FDA has reviewed the Final Post-Approval Study Report and determined that the study fulfills the commitment.



## Post Approval Studies

Occasionally FDA approves a medical device before all long-term questions about its safety and effectiveness have been answered. If these questions can only be answered by a large clinical study, FDA may approve the device for sale but require the manufacturer to continue to study its safety and effectiveness. Such a study is called a "post approval study." This page lists the post approval studies begun after January 1, 2005, and their progress. We update this page on the 5th day of each month.

[A](#) [B](#) [C](#) [D](#) [E](#) [K](#) [M](#) [O](#) [P](#) [S](#) [U](#) [V](#) [W](#) [Z](#)

59 records

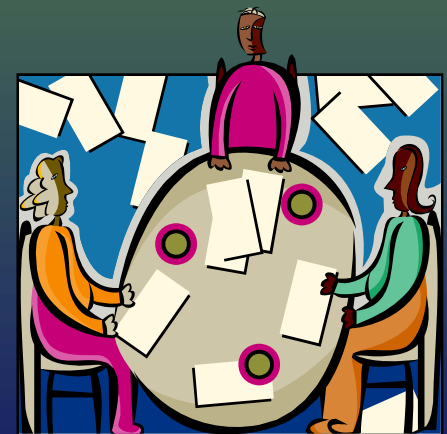
[Show All Studies](#)

[Export to Excel](#) | [F.A.Q.](#) | [Guidance Document](#)

Application Number	Applicant Name	Device Name	Medical Specialty	Date PMA Approved	Post Approval Study Description	Protocol Approved	Study Status
<a href="#">P040016</a>	BOSTON SCIENTIFIC SCIMED, INC.	LIBERTE MONORAIL AND OVER-THE-WIRE CORONARY STENT SYSTEMS	Cardiovascular	04/12/2005	EVALUATE THE LONGER-TERM OUTCOMES ASSOCIATED WITH THE LIBERTE STENT, YOU SHOULD COLLECT AND	04/12/2005	Study Completed <a href="#">Show Report</a> <a href="#">Schedule and Study Status</a>
<a href="#">P040043</a>	W. L. GORE & ASSOCIATES, INC.	GORE TAG THORACIC ENDOPROSTHESIS	Cardiovascular	03/23/2005	1) CONDUCT A POST-APPROVAL STUDY IN AT LEAST 150 PATIENTS WITH DESCENDING THORACIC	08/31/2005	Study On-time <a href="#">Show Report</a> <a href="#">Schedule and Study Status</a>
<a href="#">P040004</a>	ST. JUDE MEDICAL	ST. JUDE BIOCOR	Cardiovascular	03/05/2005	POST-APPROVAL STUDY IN	03/05/2005	Study Pending

# Postmarket Advisory Panel Updates

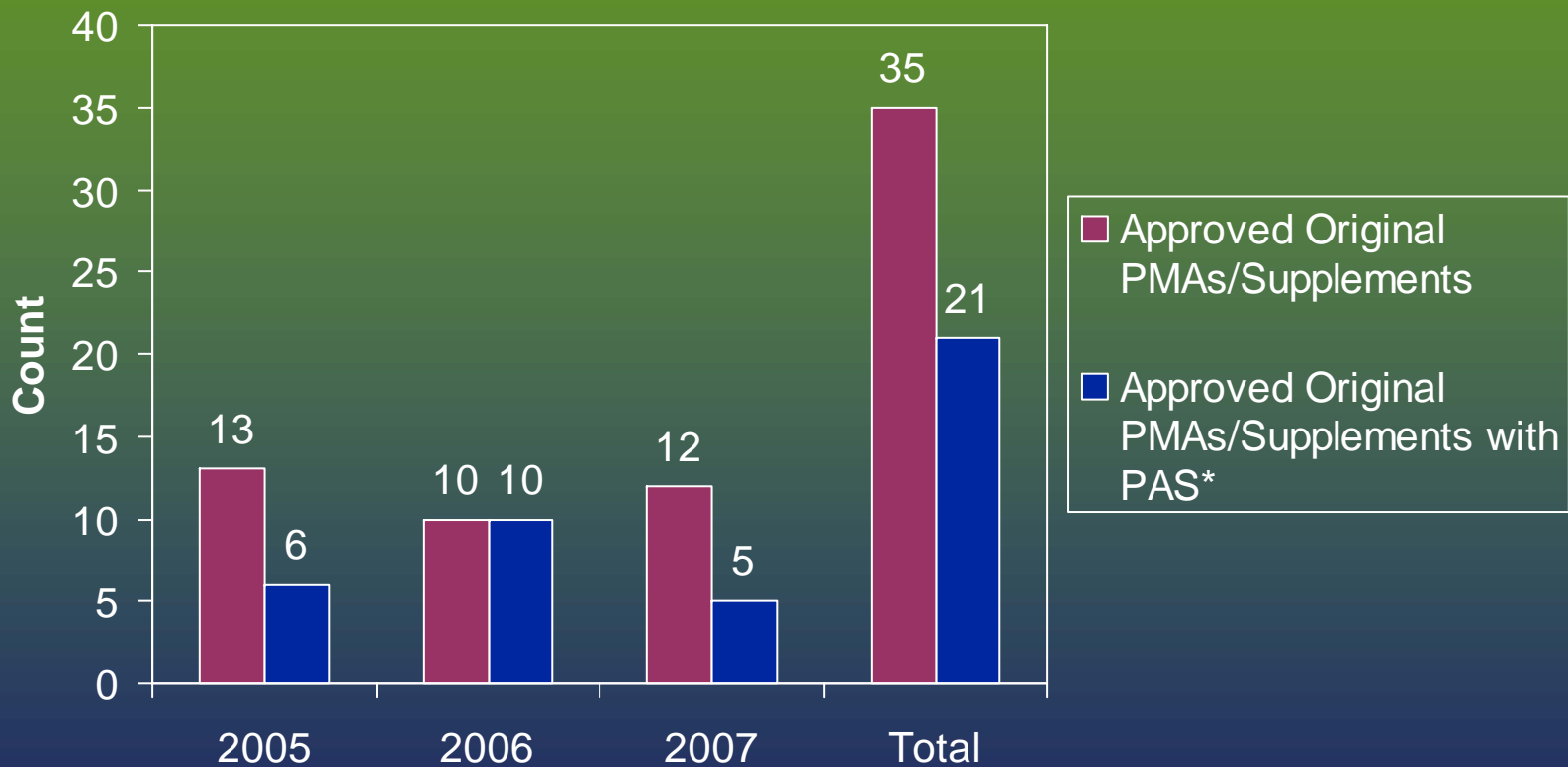
- General PAS Updates
  - First being presented today
- Specific PAS Updates
  - January 26, 2007
  - December 14, 2007



# Building Public Health Partnerships

- First FDA/FDLI PAS Conference, May 10-11, 2007
- Continued dialogue with stakeholders

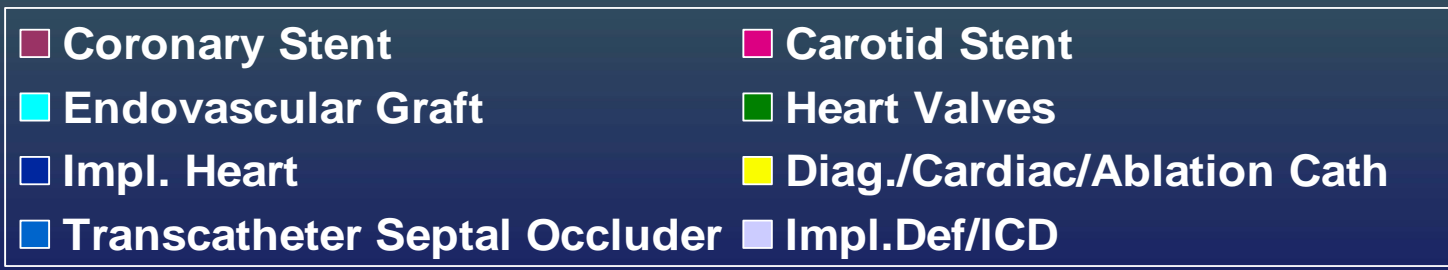
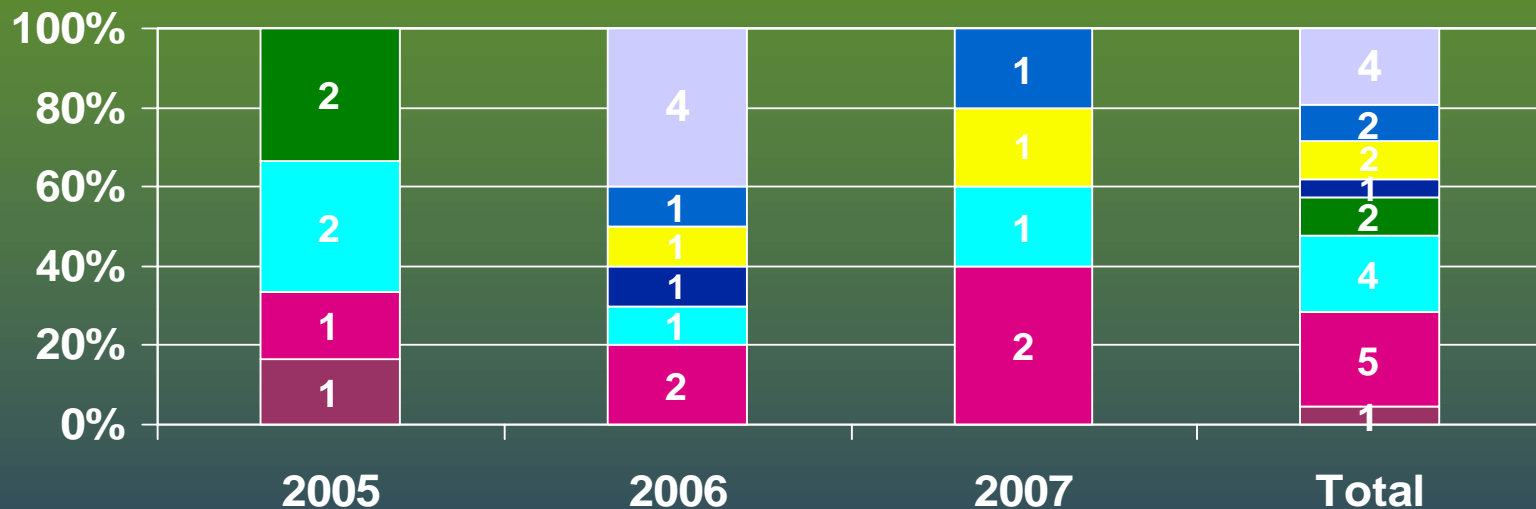
# Cardiovascular Original PMA and Supplements Approved 2005 - 2007



\*There are 21 PMAs and a total of 27 post-approval studies

As of Nov 7, 2007

# Cardiovascular Devices with Post-Approval Studies



# Distribution of PAS Study Designs

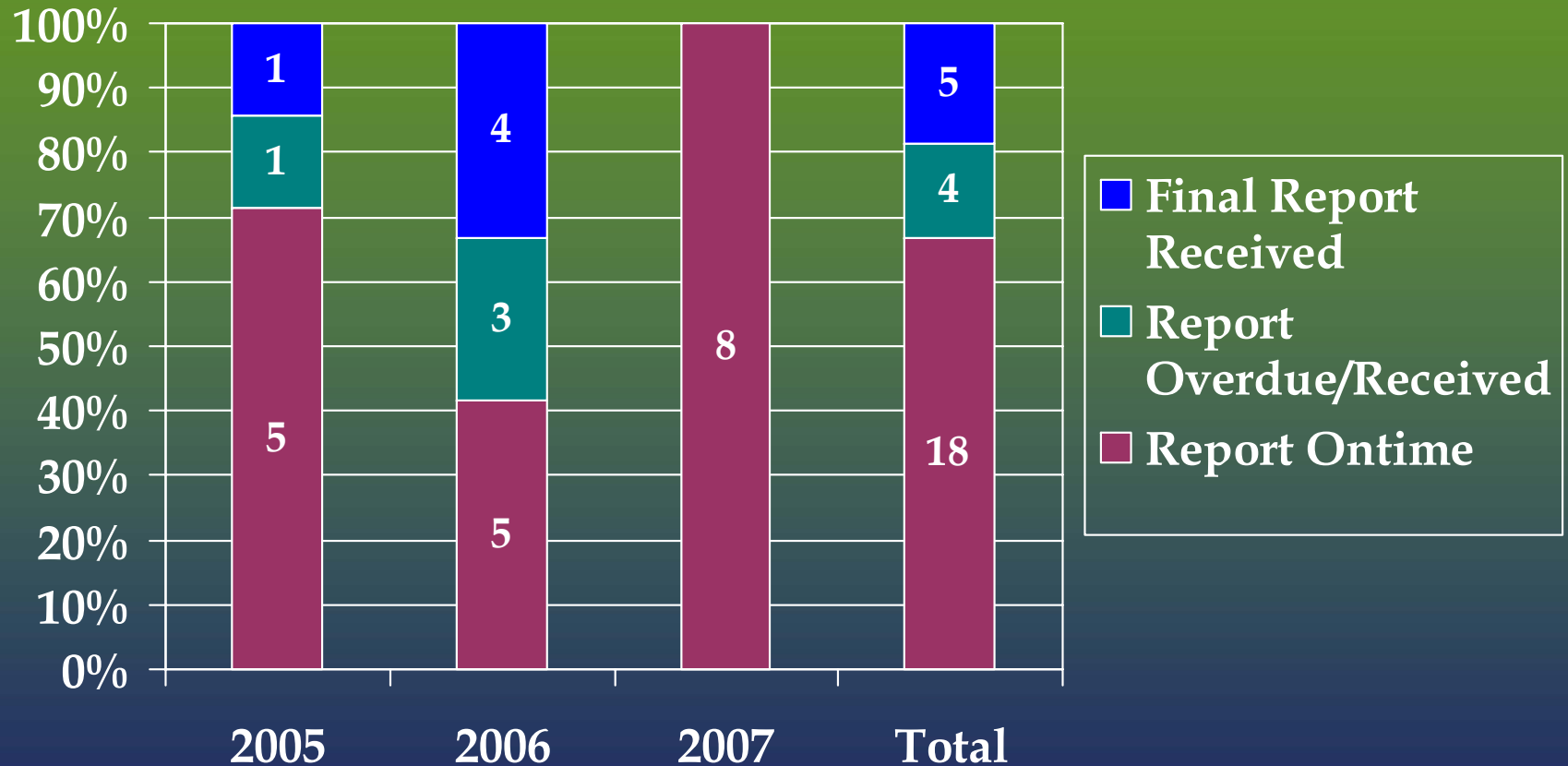
## N= 27 Studies



As of Nov 7, 2007

# Reporting Status of PAS

## N= 27 Studies



As of Nov 7, 2007

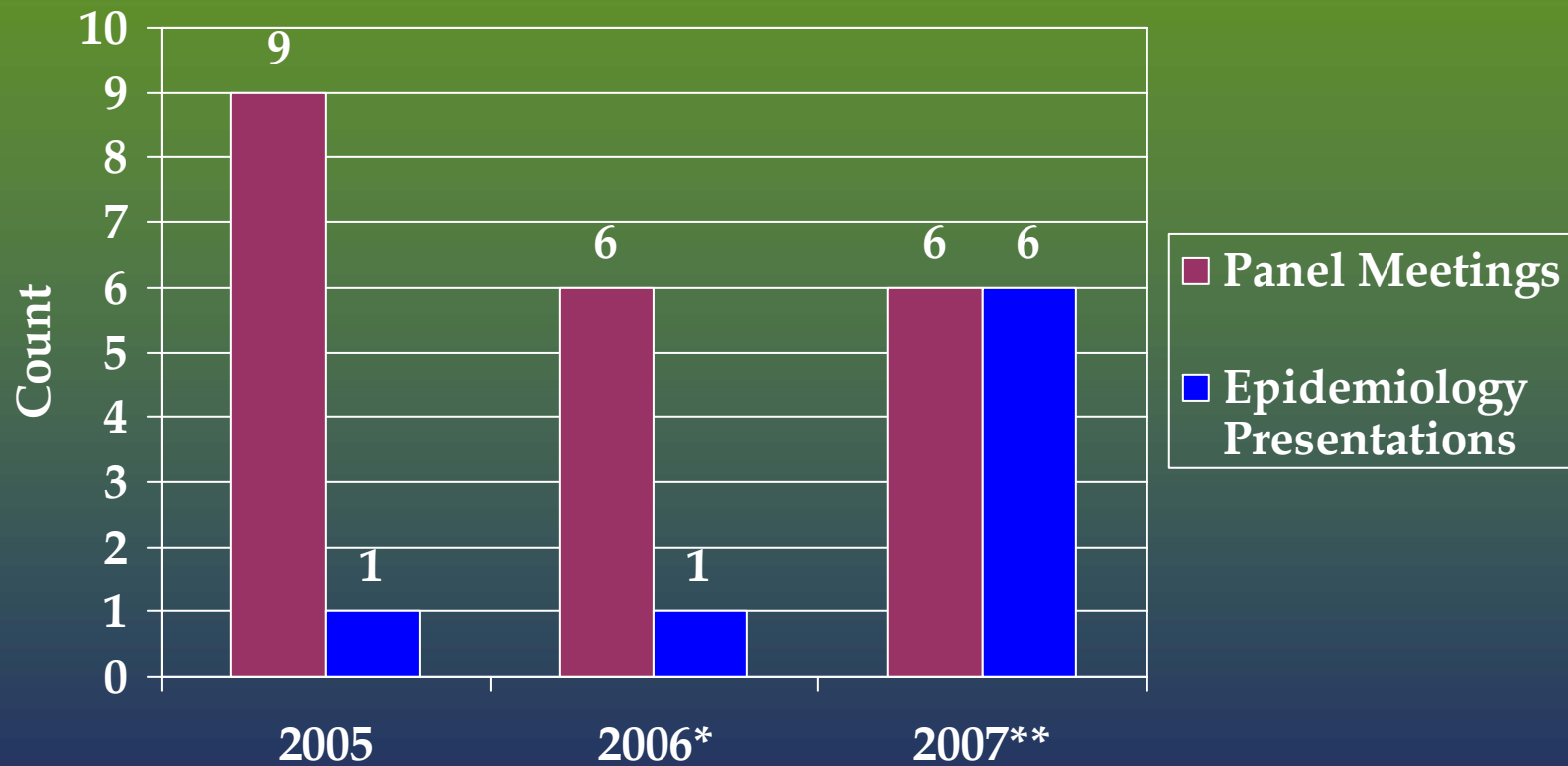
# Progress Status of PAS

N=27



As of Nov 7, 2007

# PMA/PAS Panel Presentations



\*December Presentation on Stent Thrombosis Issue; \*\*Includes November presentations

# Post- Approval Studies Vision

- Important postmarket questions are addressed
- Studies are realistic & founded on good science
- Studies are timely, accurate, & provide useful results
- Reports are clearly identified & effectively tracked
- Stakeholders are kept apprised
- Collaboration is stressed throughout
- Enforcement options are rarely used

# Epidemiology Branch

Branch Chief	Danica Marinac-Dabic, MD, PhD
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Team Leader	Nilsa Loyo-Berríos, PhD, MS
Project Manager, Postmarket	Nicole Jones
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	Cara Krulewitch, CNM, PhD
	Youlin Qi, MD MPH
	Azadeh Shoaibi, MS, MHS
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# Questions, Suggestions, Ideas?



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