



Post-Approval Studies Program Update

Orthopedic and Rehabilitation Devices Advisory Panel, May 12, 2011

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Post-Approval Studies

- Clinical study or other investigation required in an approval order to gather specific information to address precise study objectives
- Imposed by order under the authority of Section 513(a)(3)(C) of the Federal Food, Drug, and Cosmetic Act (FDC Act) (21 U.S.C. § 360c(a)(3)(C))
 - Added by the Food and Drug Administration Modernization Act (FDAMA), and the post-approval requirements regulations at 21 C.F.R. Part 814.82(a)

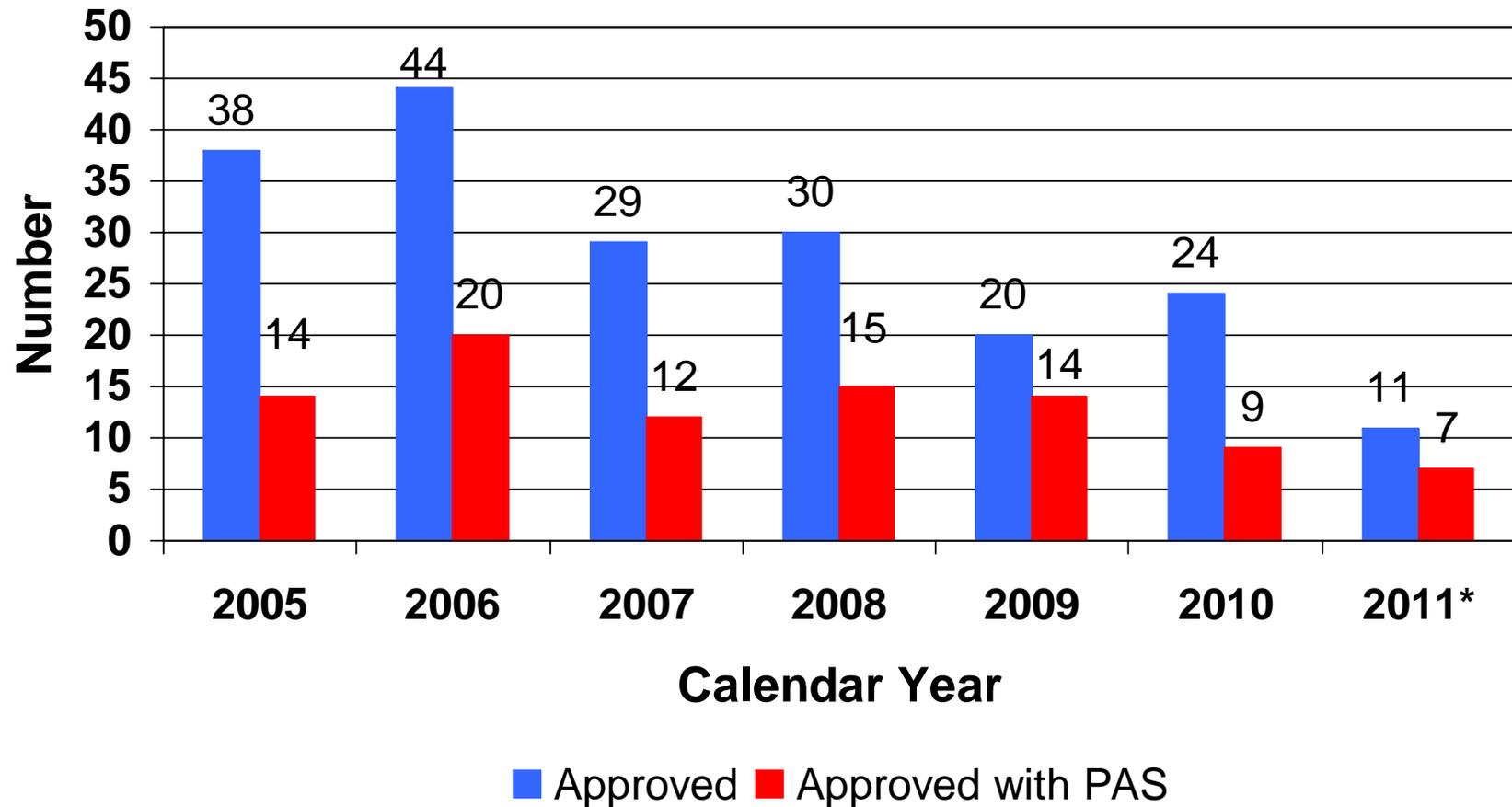
Post-Approval Studies – Established Need

- Gather essential postmarket information
 - Longer-term performance including effects of re-treatments & product changes
 - Real-world device performance (patients and clinicians)
 - Effectiveness of training programs
 - Sub-group performance
 - Outcomes of concern (safety and effectiveness)

Recent PAS Developments

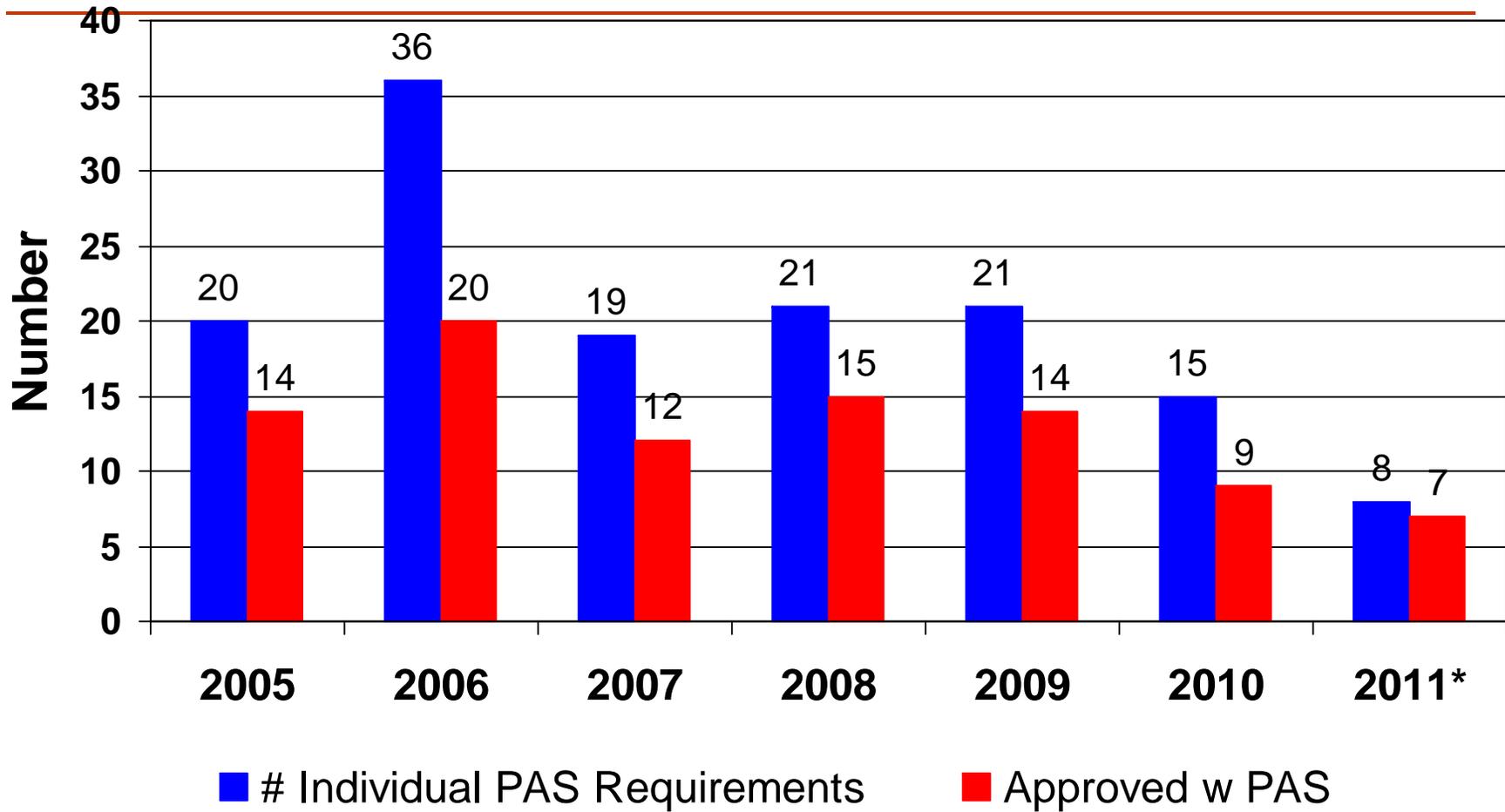
- 2005 Integrated PAS program established
- 2005 Began raising scientific rigor of PAS
- 2006 Developed and instituted PAS tracking
- 2006 Issued PAS Guidance document
- 2007 Created PAS public website
- 2007 Instituted Advisory Panel updates
- 2008 Initiated BIMO inspections of PAS
- 2008 Increased focus on infrastructure building
- 2009 Increased focus on methods development
- 2010 MDEpiNet Initiative
- 2011 ICOR Initiative

Number of Approved Original PMAs and Panel-Track Supplements (PTS), 2005-Present



*As of 5/9/2011

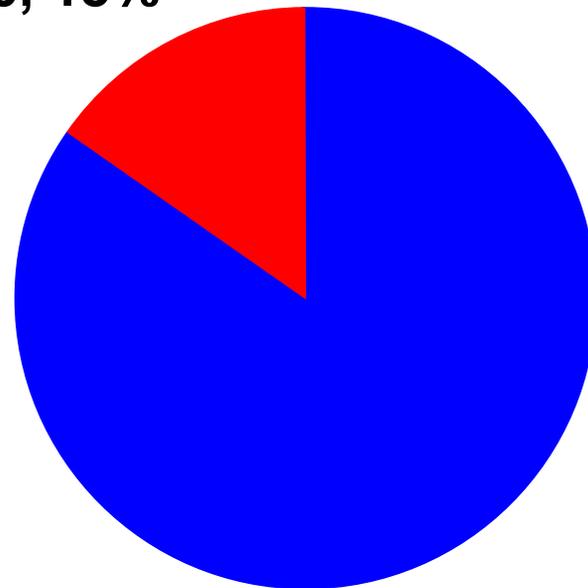
Number of Original PMAs and PTS Approved with PAS Order and Number of Individual Requirements, 2005 to Present



*As of 5/9/2011

Compliance with PAS Requirements Issued 2005 to Present, N=198

30, 15%



■ In-Compliance
■ Non-Compliance

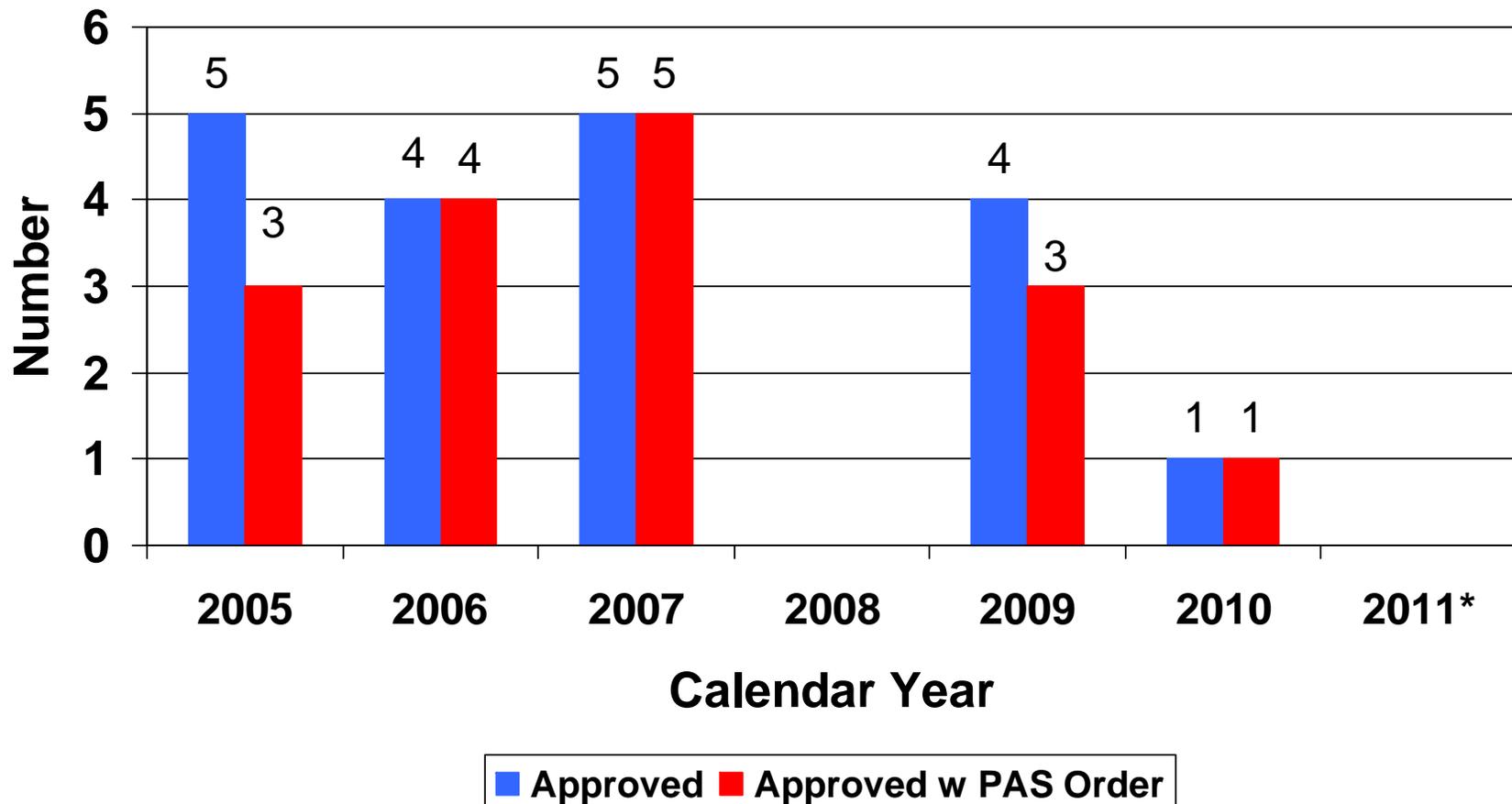
168, 85%

As of 5/9/2011

PAS for Orthopedic Devices

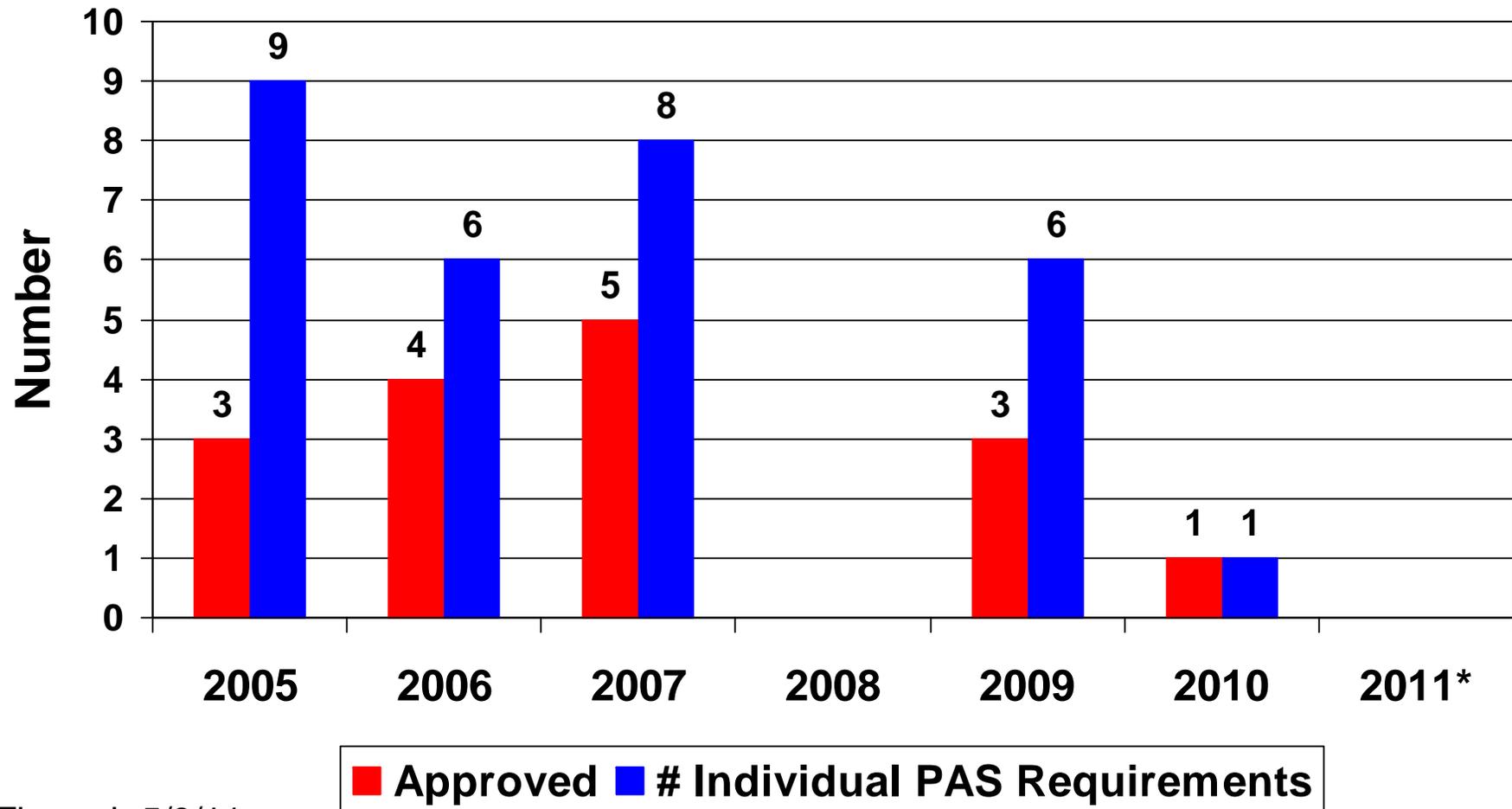


Approved Orthopedic Original PMAs and Panel-Track Supplements



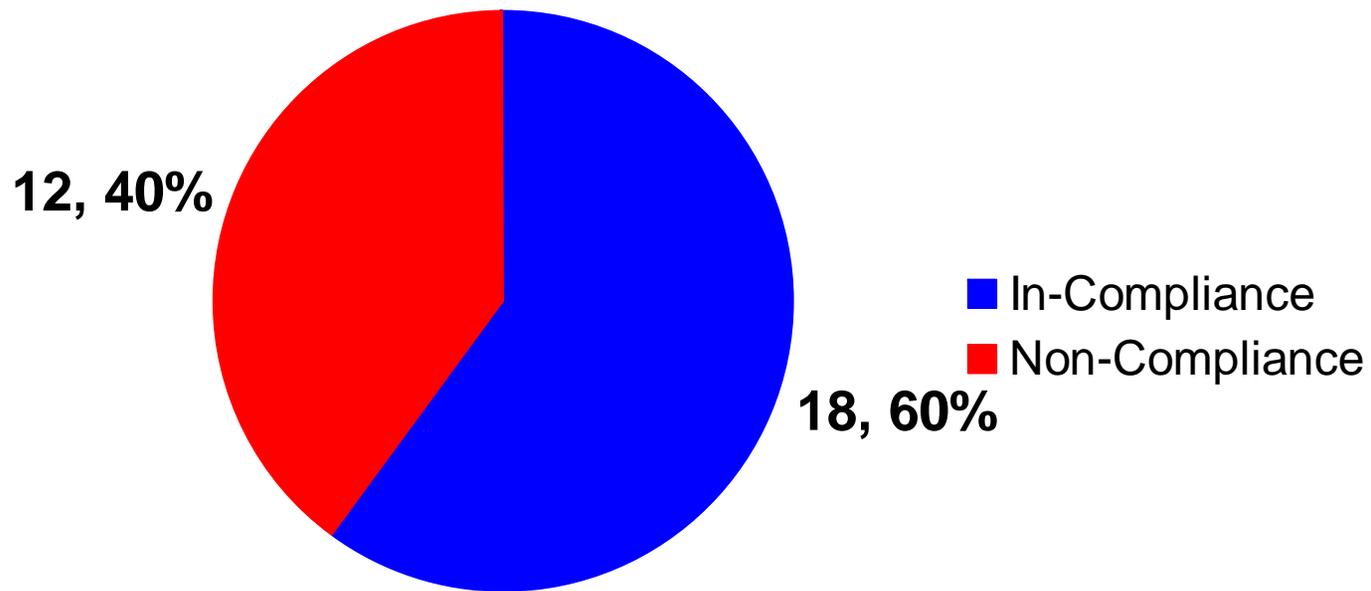
* Through 5/9/11

Orthopedics Original PMAs and Panel-Track Supplements Approved with PAS Requirements



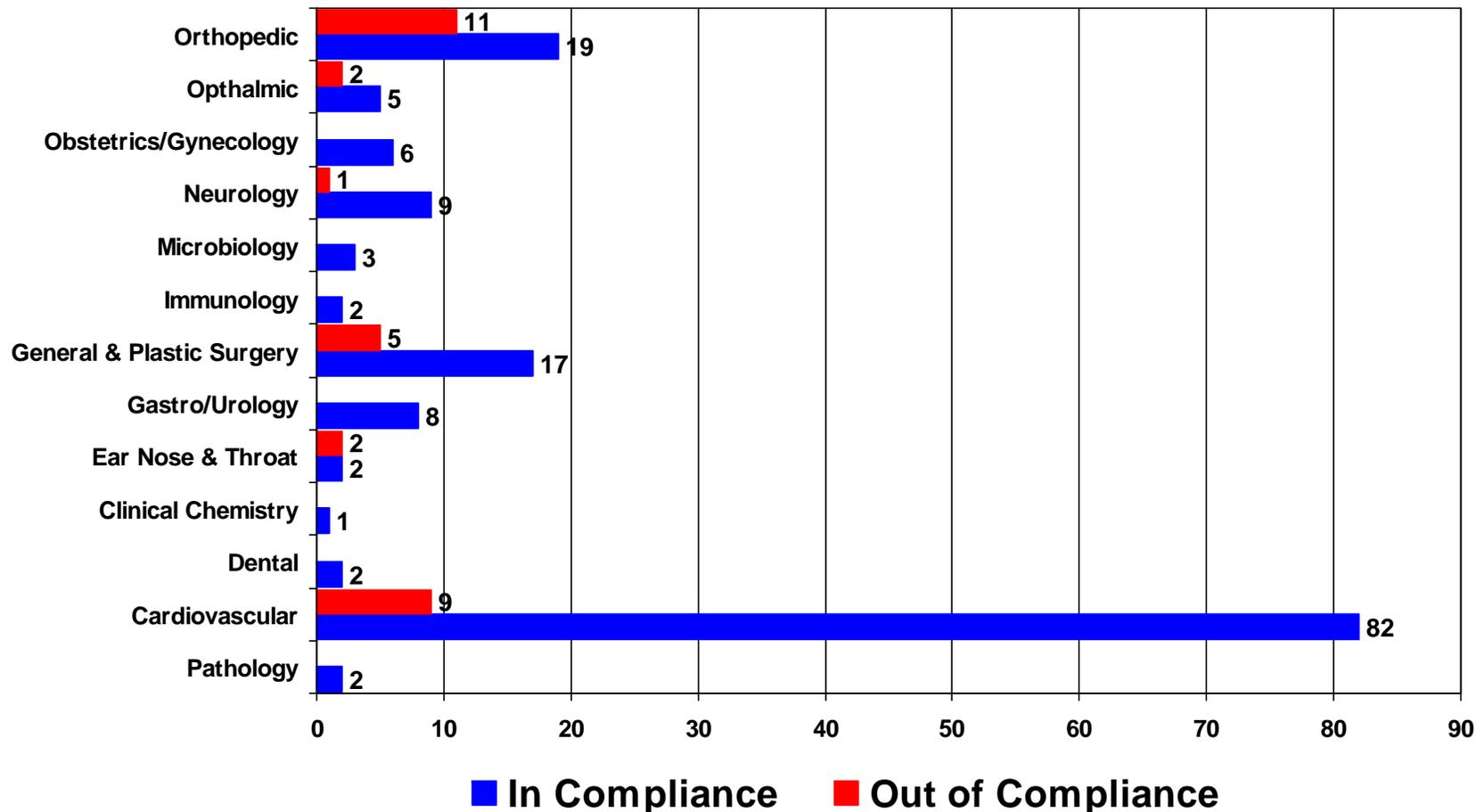
•Through 5/9/11

Compliance with PAS Orthopedic Requirements Issued 2005 to Present N=30



As of 5/9/2011

Number of PAS by Device Area and Study Status



Recent CDRH Orthopedic Efforts

- Identify and evaluate existing U.S. orthopedic implant registries
- Assess HMO capabilities to study orthopedics
- Explore the utility of OUS orthopedic registries
- Assess orthopedic device identification (registry-specific methods)
- Explore the utility of CMS data and linking
- Quantify prognostic ability of models that integrate all existing data (premarket, PAS, registry, claims, published literature)
- Apply automated surveillance techniques
- International Consortium of Orthopedic Registries₁₃ (ICOR)

MDEpiNet Initiative – launched 2010

- **M**edical **D**evice **E**pidemiology **N**etwork
- To bridge evidentiary gaps and develop datasets and innovative methodological approaches for conducting analytic studies to improve FDA understanding of safety and effectiveness of medical devices throughout their life cycle through leverage of expertise from academia and other stakeholders.
- 2nd FDA Public Meeting - held April 25, 2011
- MDEpiNet Public Private Partnership

ICOR Initiative

- Establish International Consortium of Orthopedic Registries (ICOR) to:
 - leverage data from existing registries
 - advance methods to study device performance and patient outcomes
 - help enhance and harmonize the registry data worldwide
 - improve research collaboration
- FDA Public Workshop - held May 9, 2011
 - 35 registries present
 - All major stakeholders



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Section 522 of FFDCCA

Authority to order postmarket surveillance of any class II and class III medical device that meets any of the following criteria:

- Failure of the device would be reasonably likely to have a serious adverse health consequence
- Expected to have significant use in pediatric populations
- Intended to be implanted in the body for more than one year
- Intended to be a life-supporting device used outside of a user facility

Moving Forward

- The 522 Order
 - Section 522 of the FD&C Act allows FDA to order manufacturers to conduct postmarket surveillance for devices under certain circumstances
 - CDRH issued 522 orders to all MoM total hip manufacturers on May 6, 2011, asking them to address specific questions relating to:
 - Types and rates of adverse events in patients with MoM total hips
 - Ion levels at baseline and over time of MoM hip patients, including:
 - Patients with revisions compared with those without revision
 - Patients with pain/local ARMD compared with those without
 - Association of demographics/clinical characteristics to metal ion levels
 - Modes and causes of failure