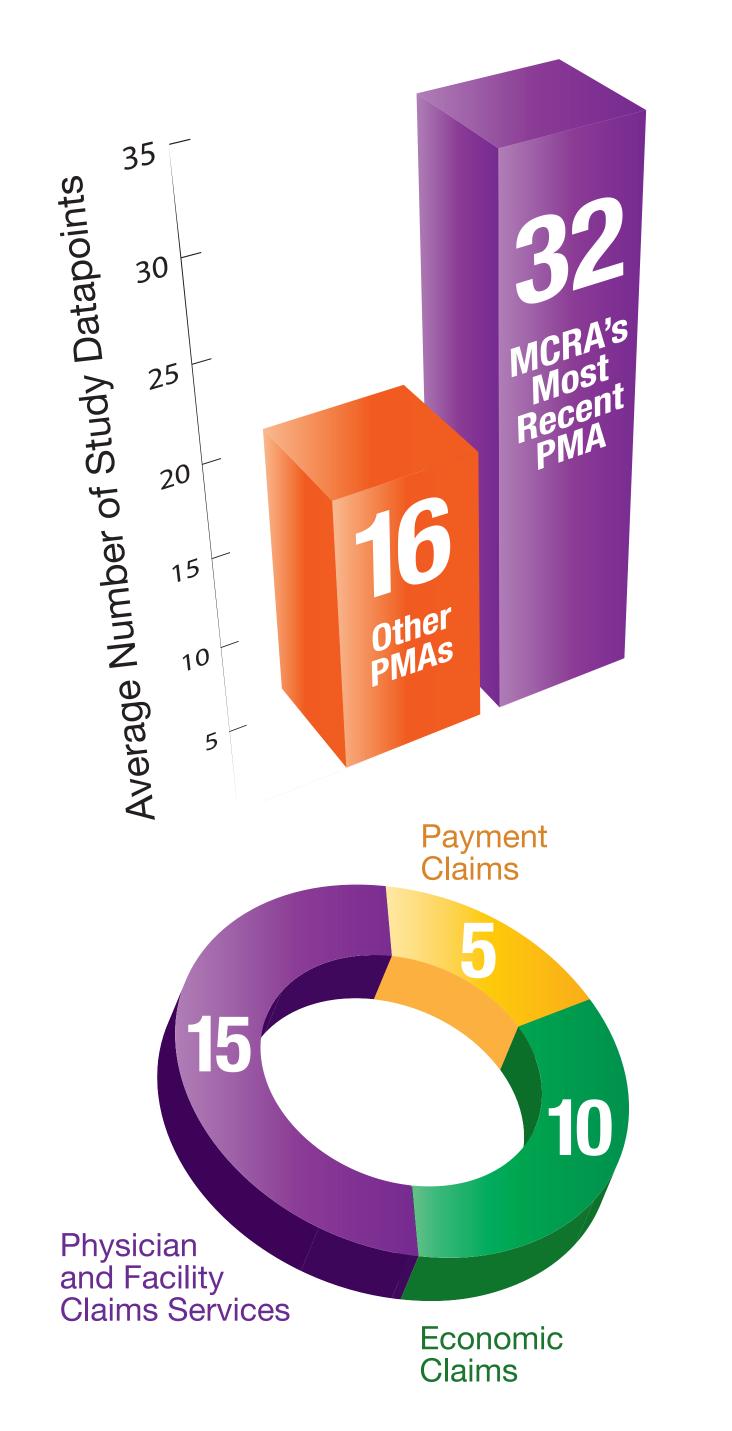


# Recent MCRA Spine PMA Case Study Success

MCRA is Superior
Leads Rigorous And Thorough Randomized Prospective US IDE Clinical Studies.



## 50% More Outcomes

Clinical Outcomes Studied

**Collected More** Health Economic-Related Assessments (30) than any other Spine PMA

Reimbursement Endpoints

#### Reducing Bias

• One of only 2 spine PMAs with an independent Clinical Events Committee to establish independence

### Quality Assurance & GMP

- Created Quality System
- Prepared PMA
- ø Findings at PMA Audit

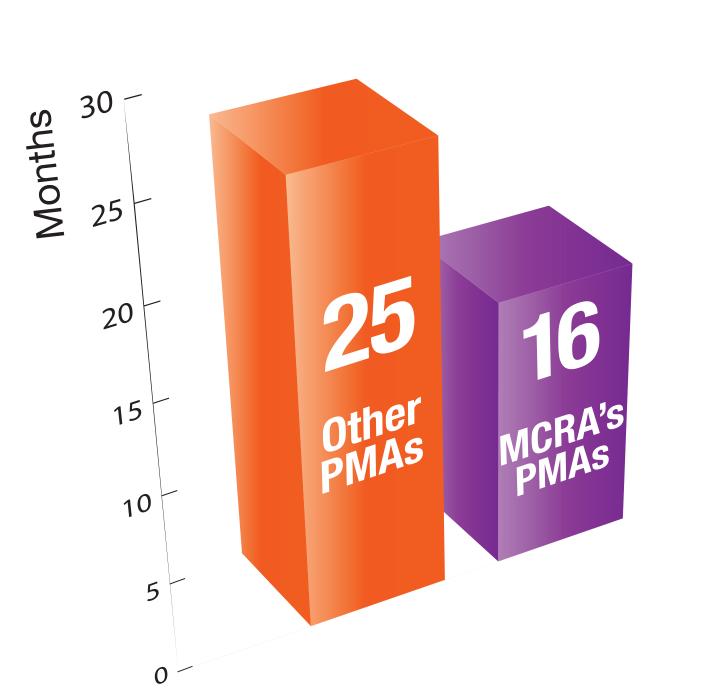
# MCRA is Faster

Since 2000, There Have Only Been 10 Spine PMA Approvals.



# 1 YEAR FASTER

IDE Approval to PMA Approval



40% FASTER

PMA Review Time

Achieved Level 1 Comparative Effectiveness with >100 Clinical, Radiographic, and Economic Endpoints Organized & Presented Clinical Data for Faster FDA Approval