

# 510(k) Benchmarking Survey

Nancy Singer &  
Jim Dietrich  
Compliance-Alliance.com  
Nancy\_Singer@juno.com



Dan Olivier  
Certified Compliance Solutions  
certifiedcompliance.com  
doliver@certifiedcompliance.com

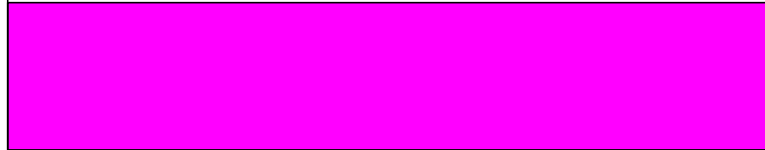


# Demographics

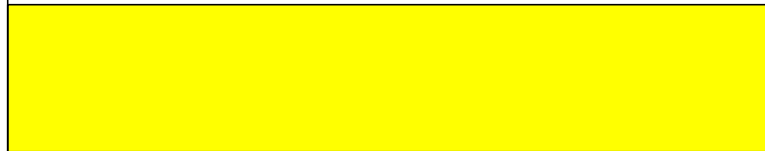
- Survey conducted June 2008
- 25 respondents in Gastroenterology-Urology Devices Large, medium and small firms were represented

# Color Legend

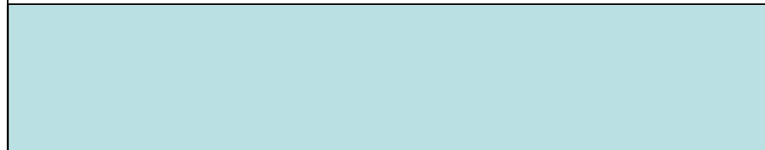
**Significant  
Majority**



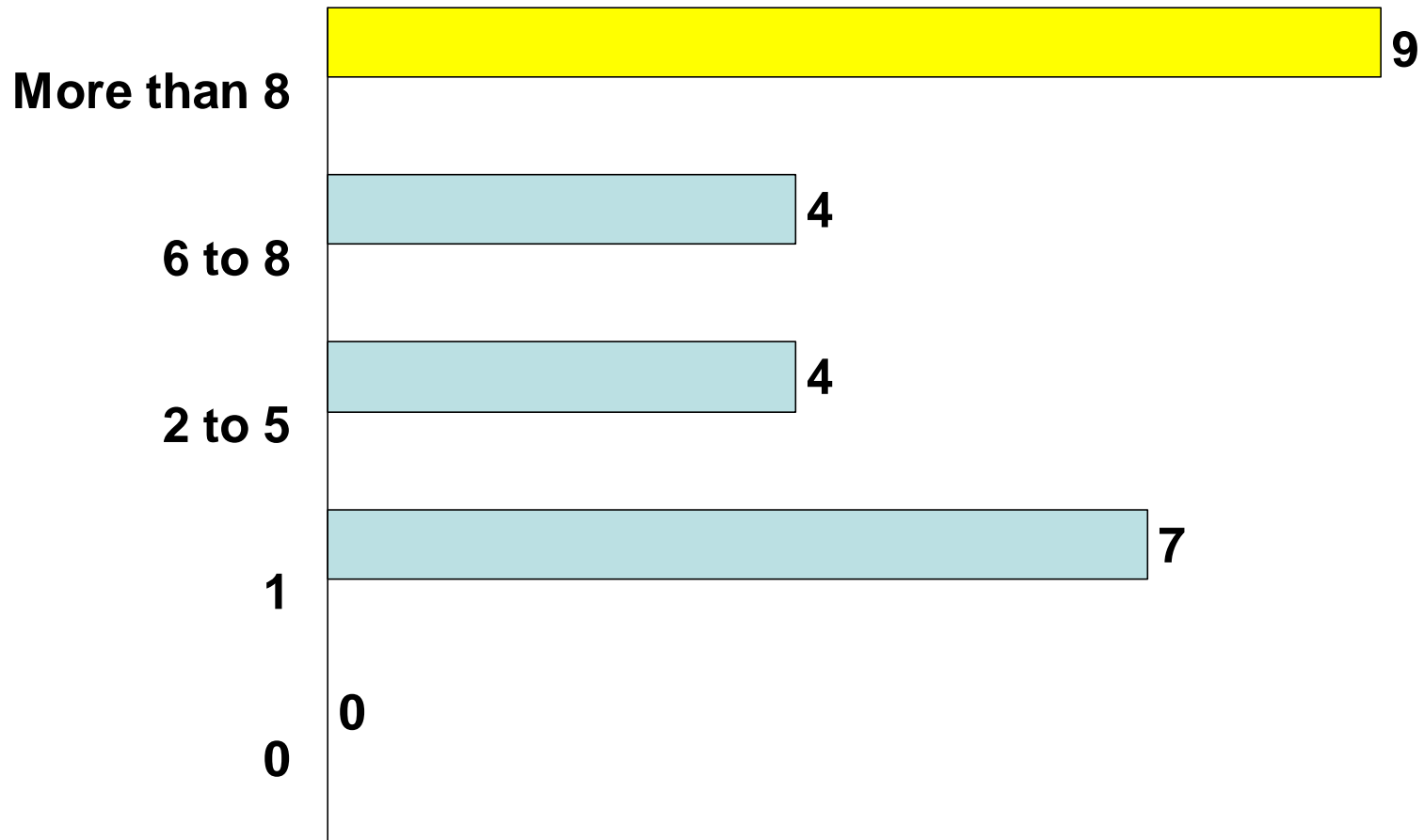
**Moderately  
Significant**



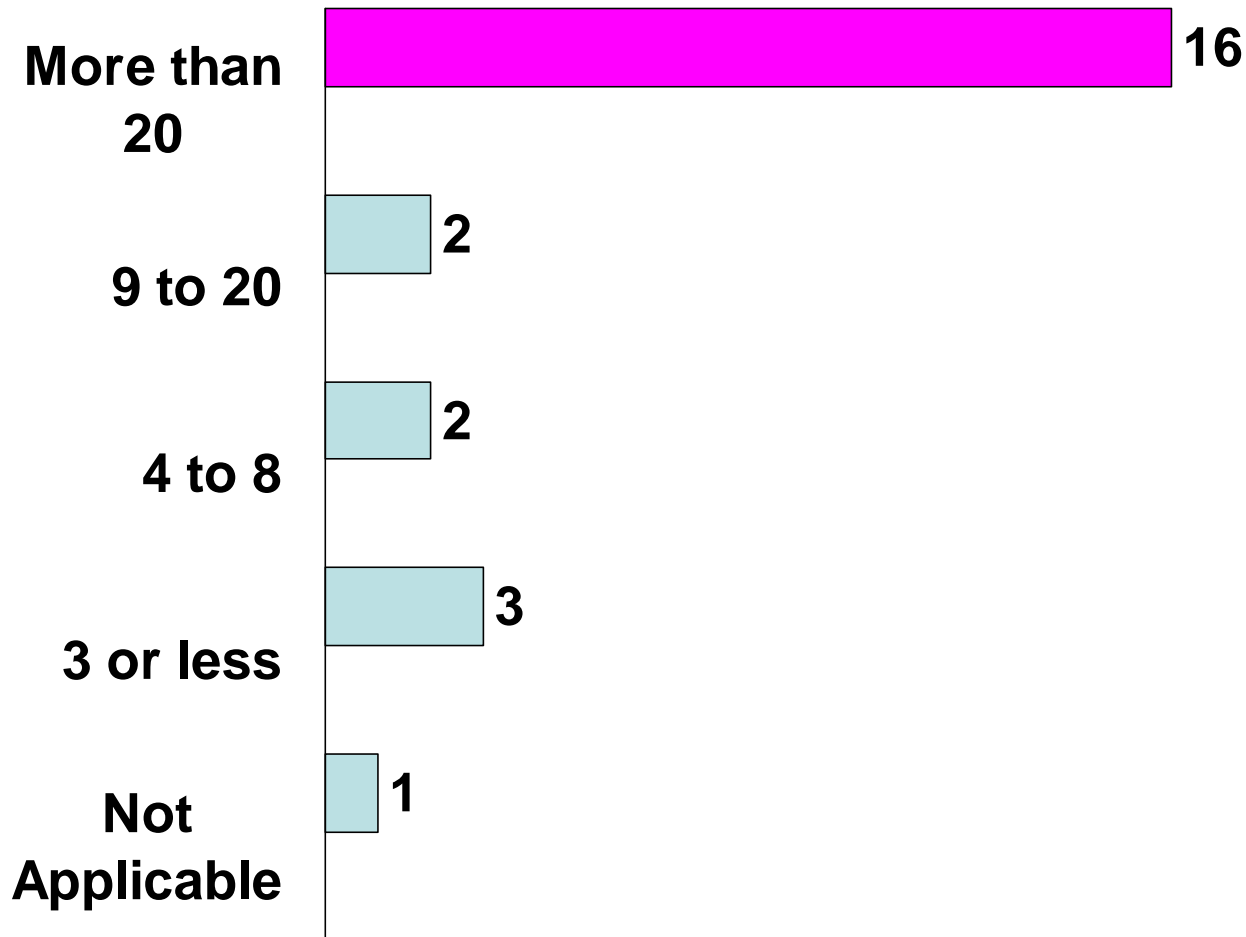
**Least  
Chosen  
Answers**



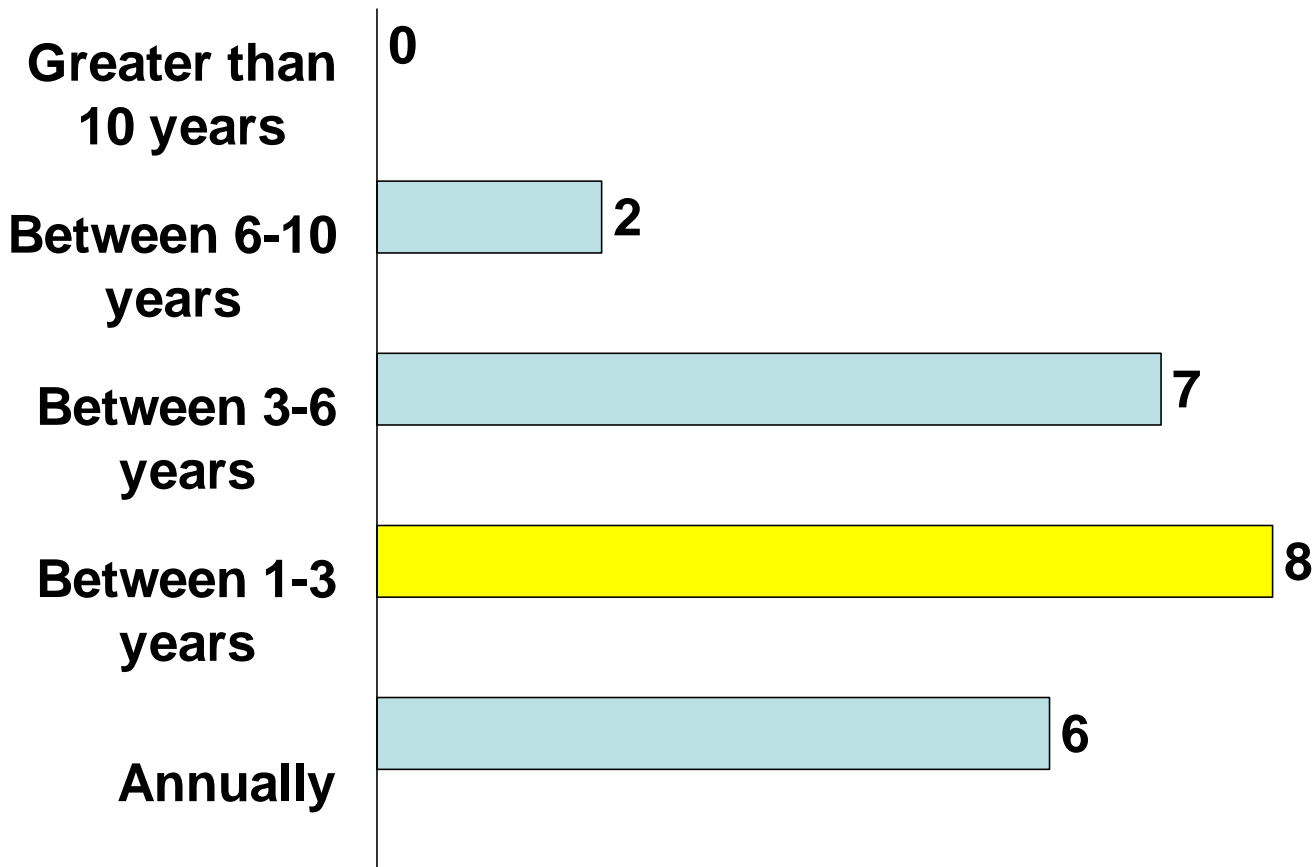
# Number of 510(k)s Submitted Annually



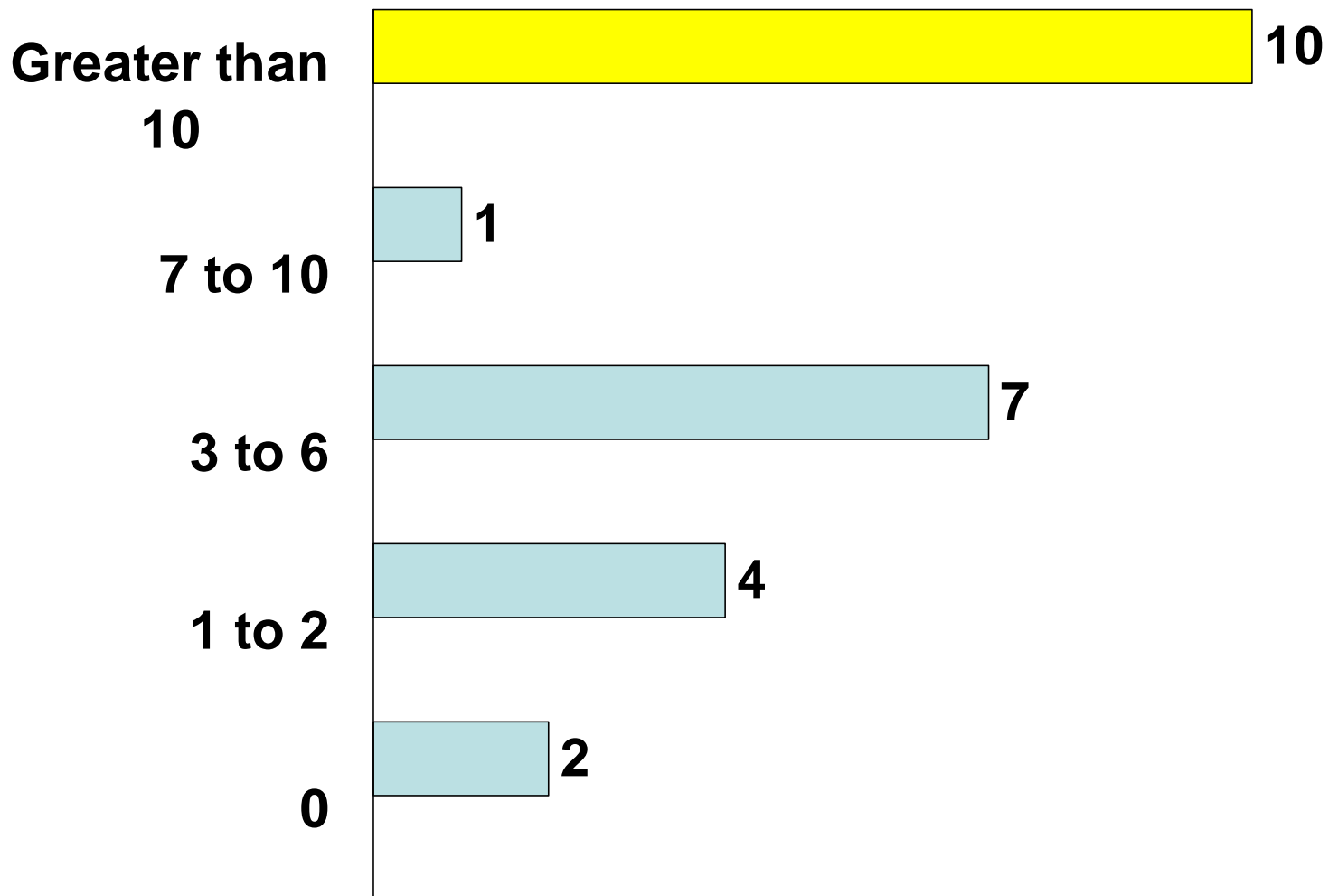
# Number of 510(k)s Cleared



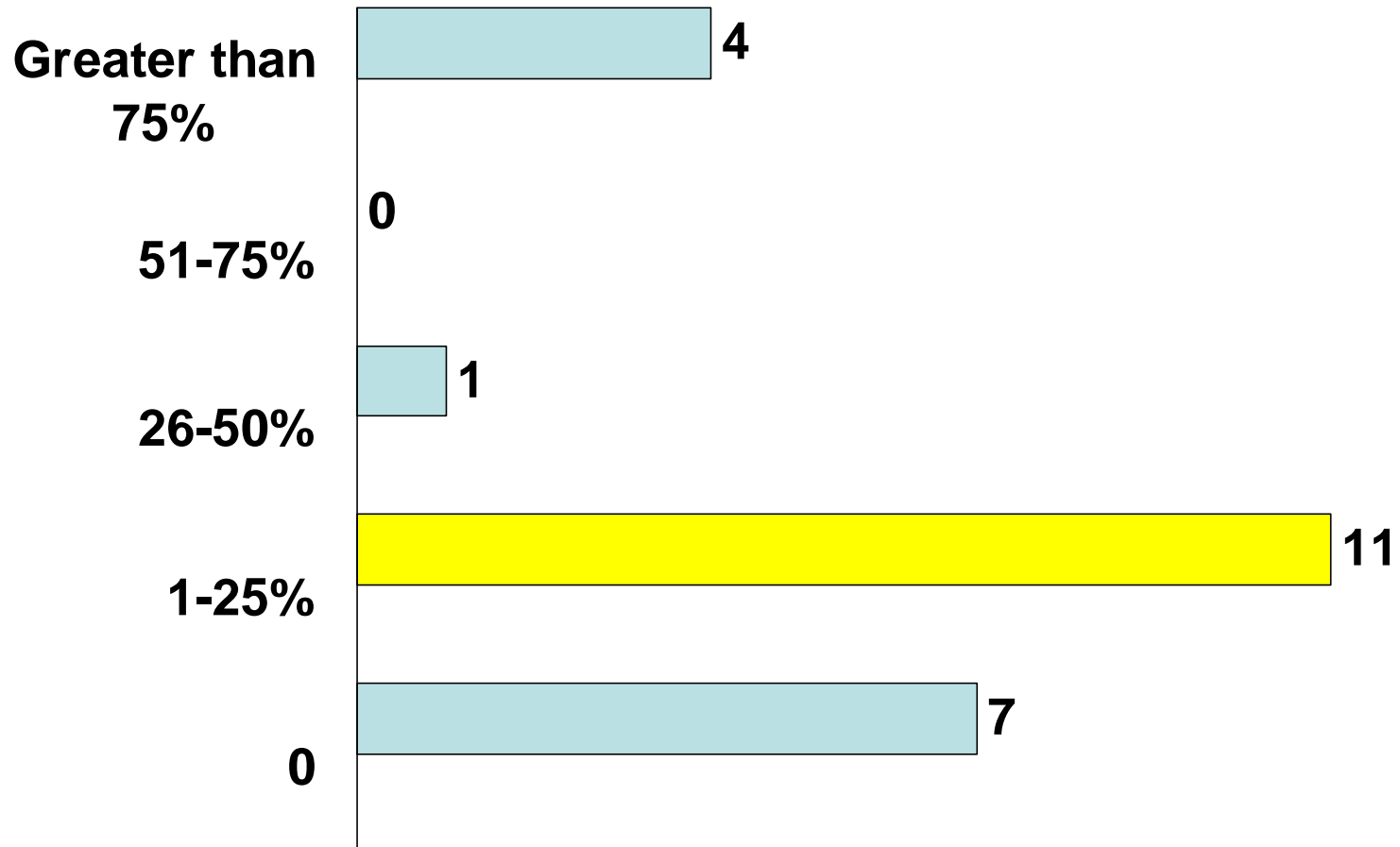
# How Often Firms Submitted 510(k)s for Changes to their Products



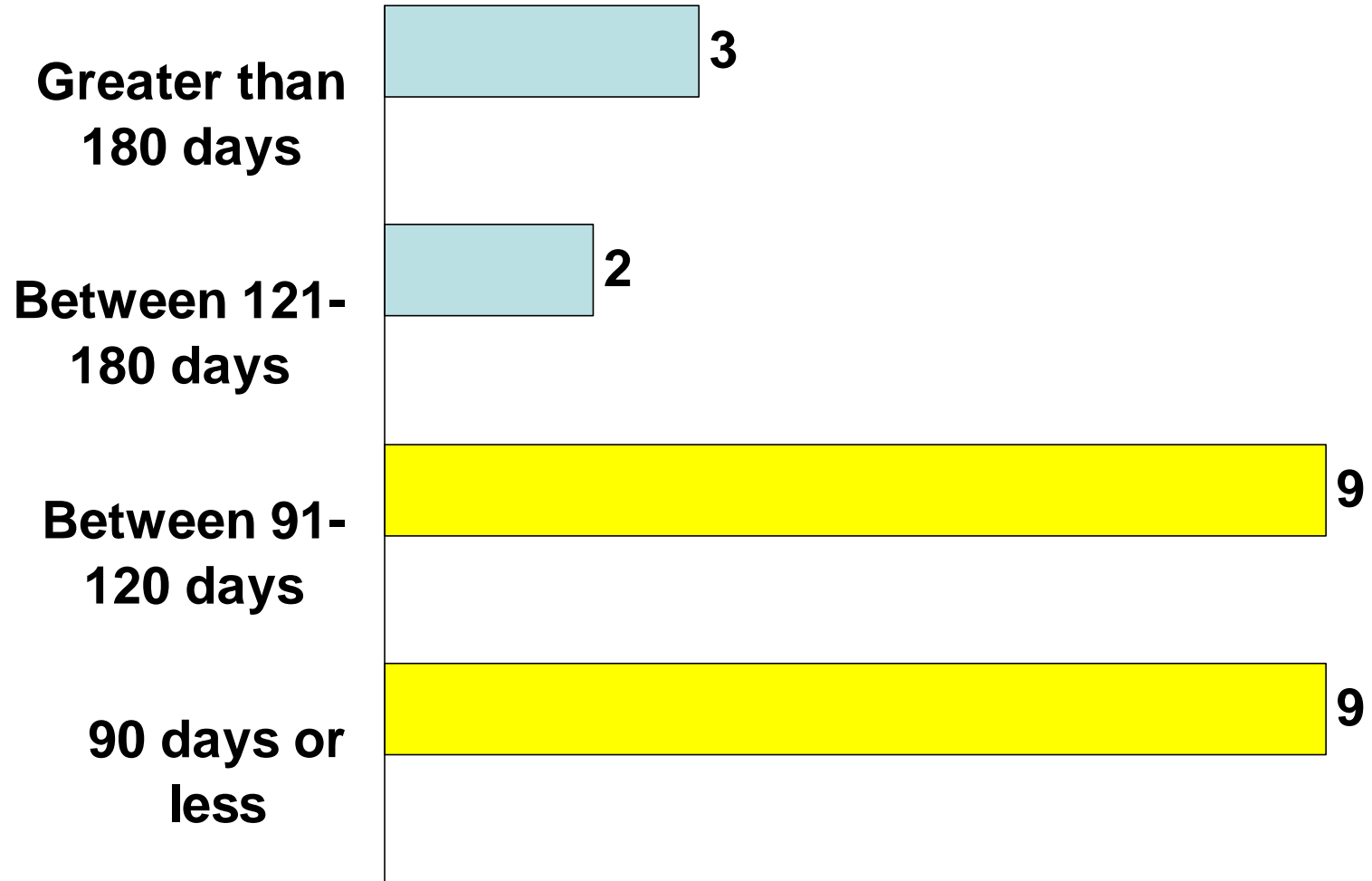
# Number of Submissions in the Last 3 Years



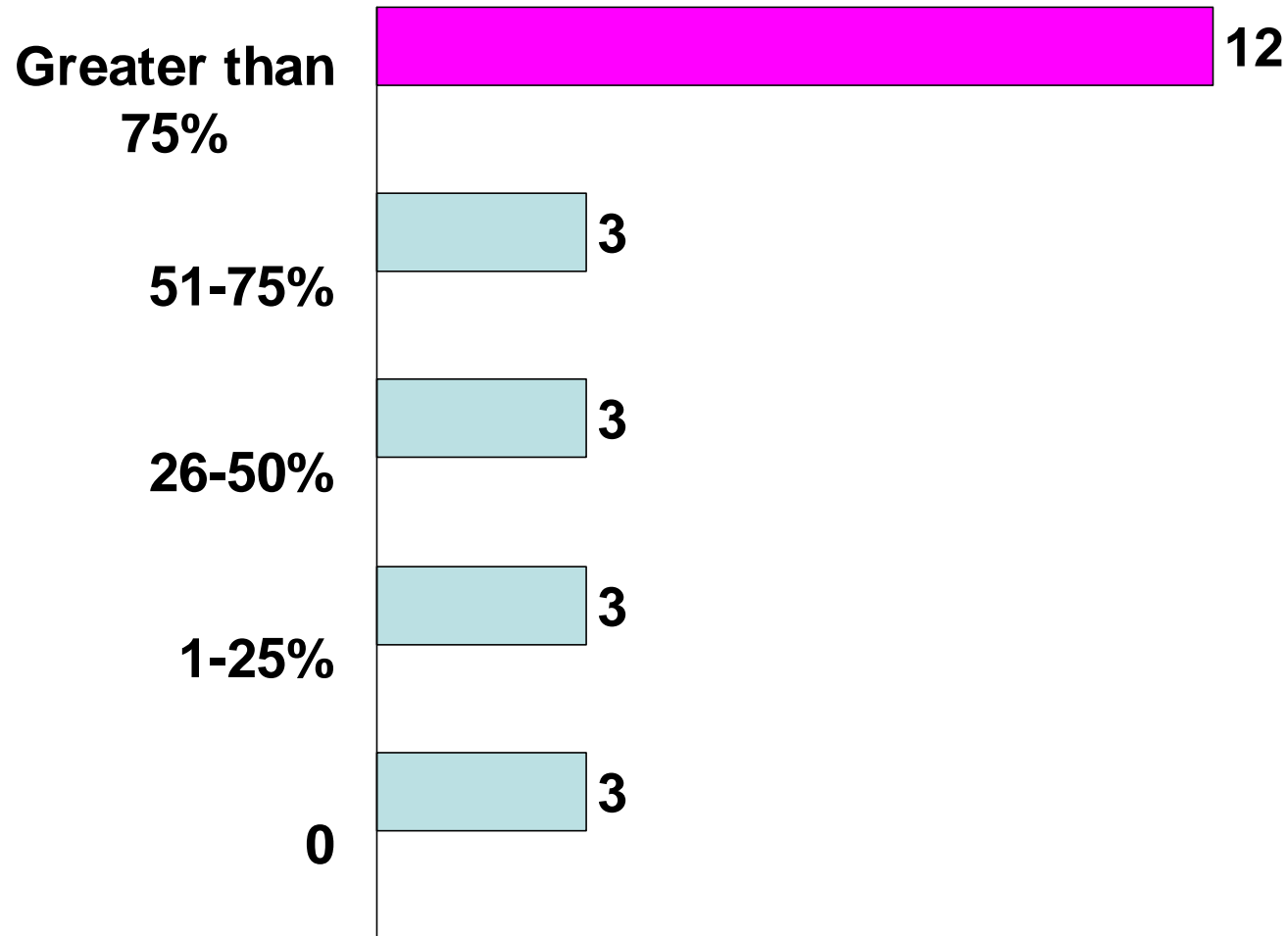
# Percent of Submissions Where FDA Didn't Ask for Additional Data



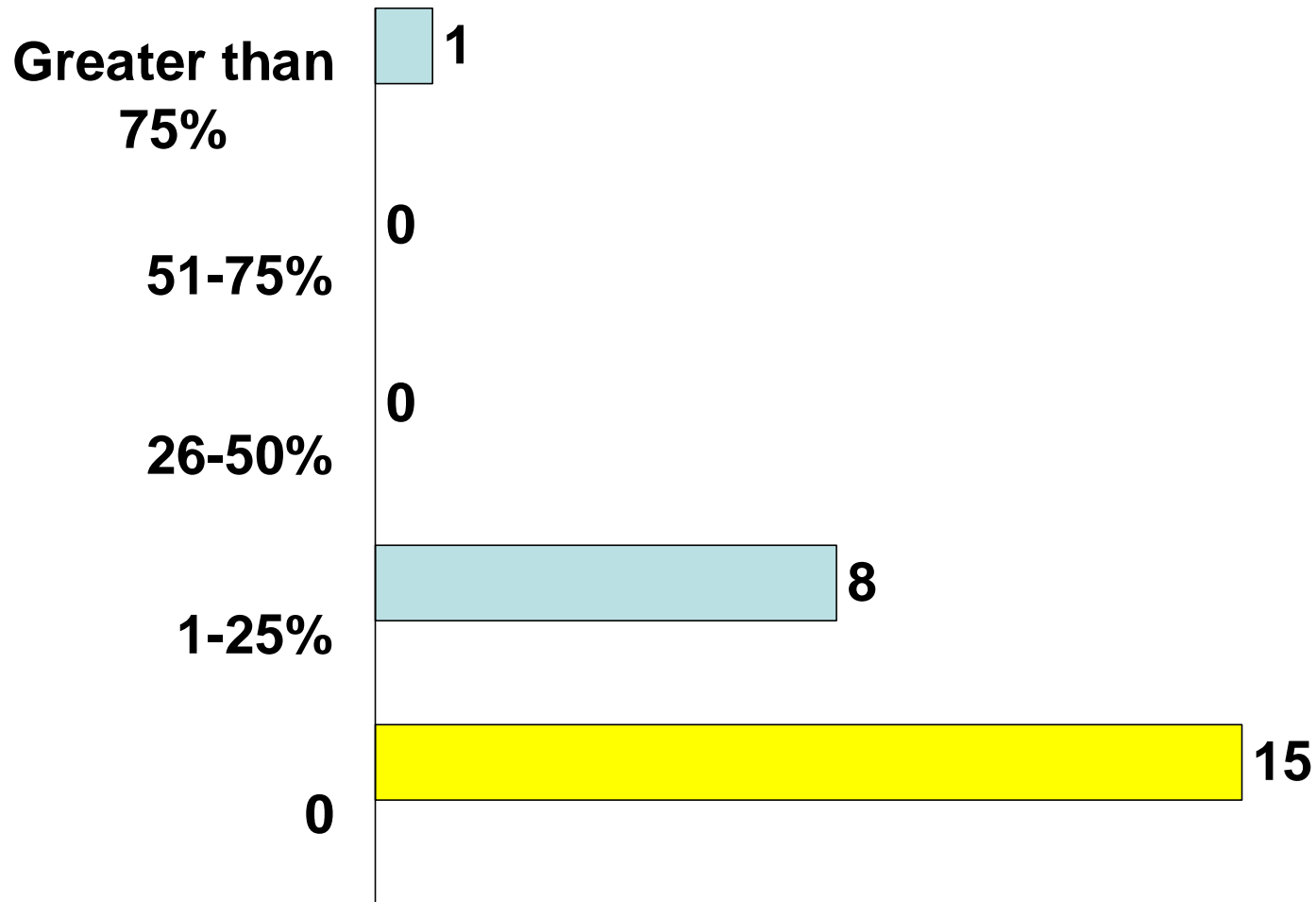
# Time from 510(k) Submission to Receiving a Clearance



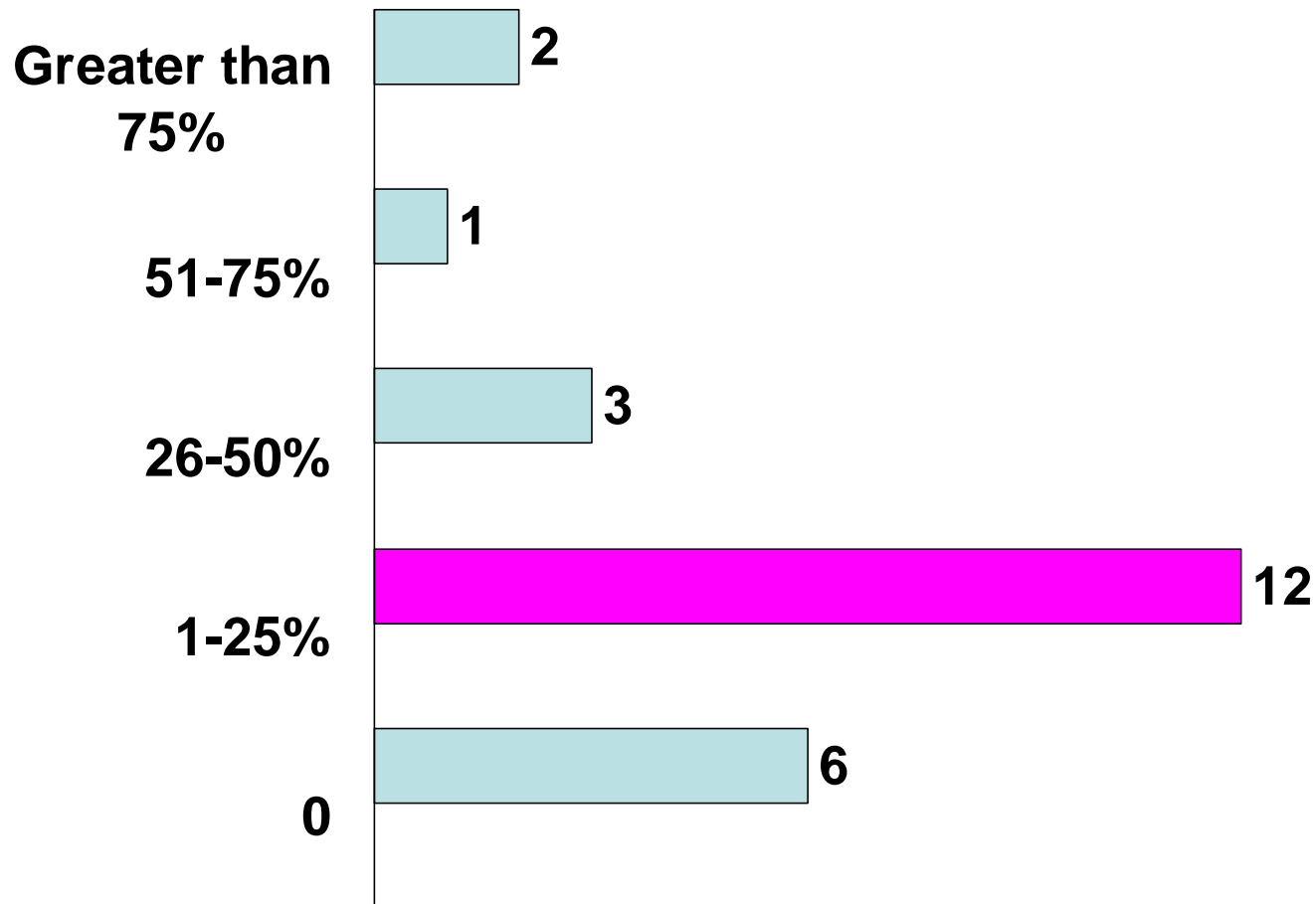
# In the past 3 years, the percentage of 510(k) submissions that were “Traditional”



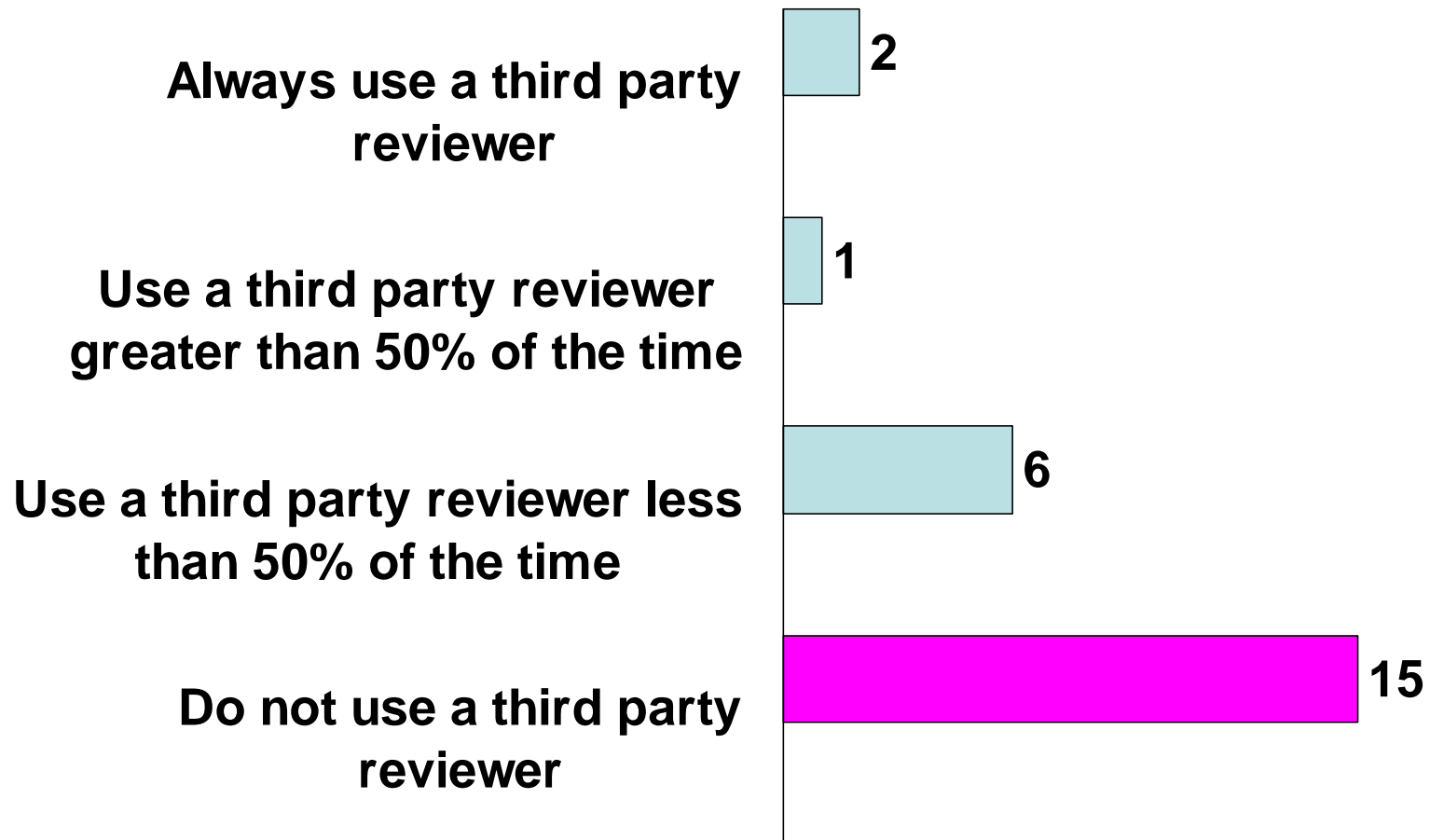
In the past 3 years, the percentage of 510(k) submissions that were “Abbreviated”



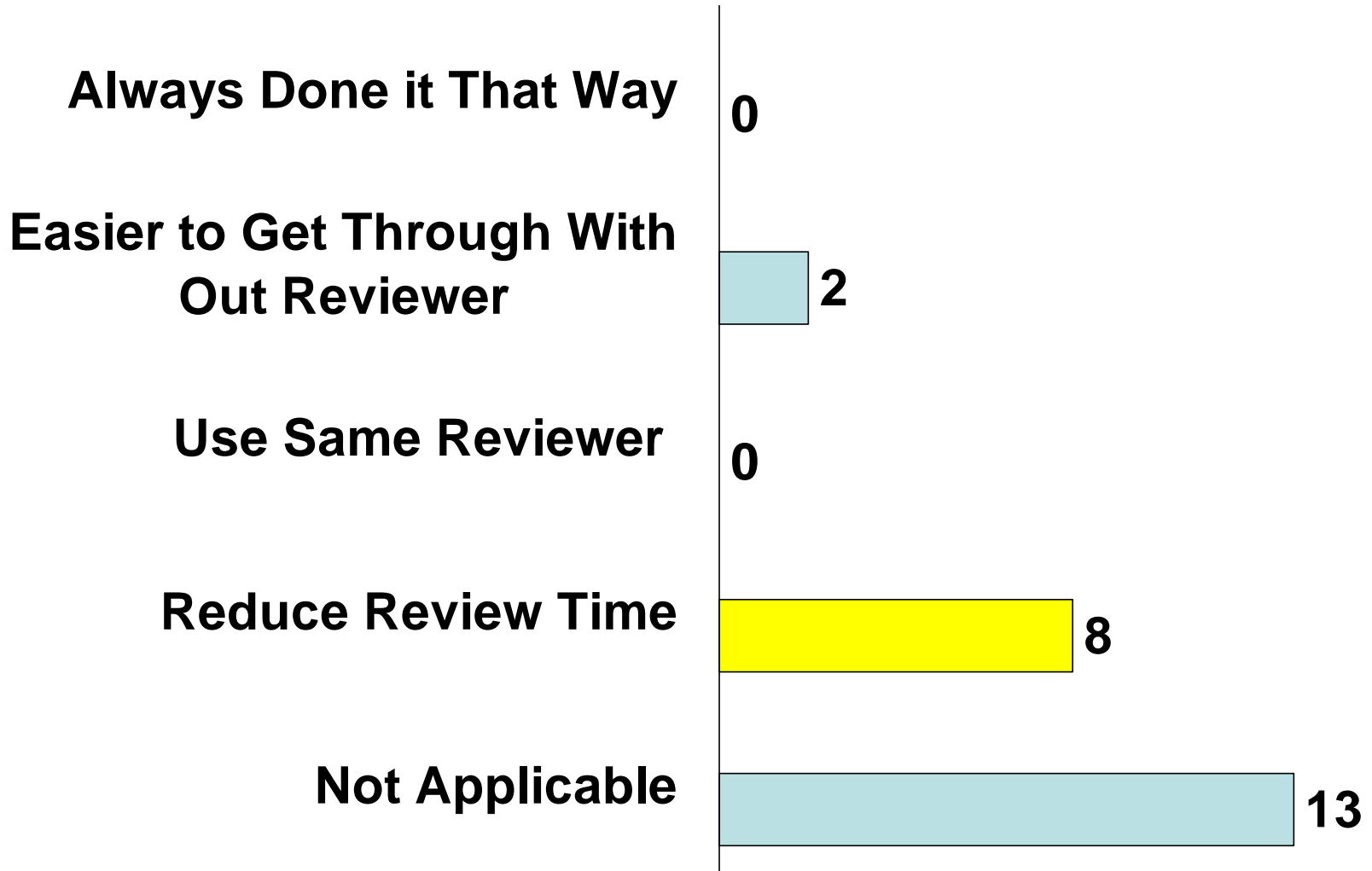
In the past 3 years, the percentage of 510(k) submissions that were “Special”



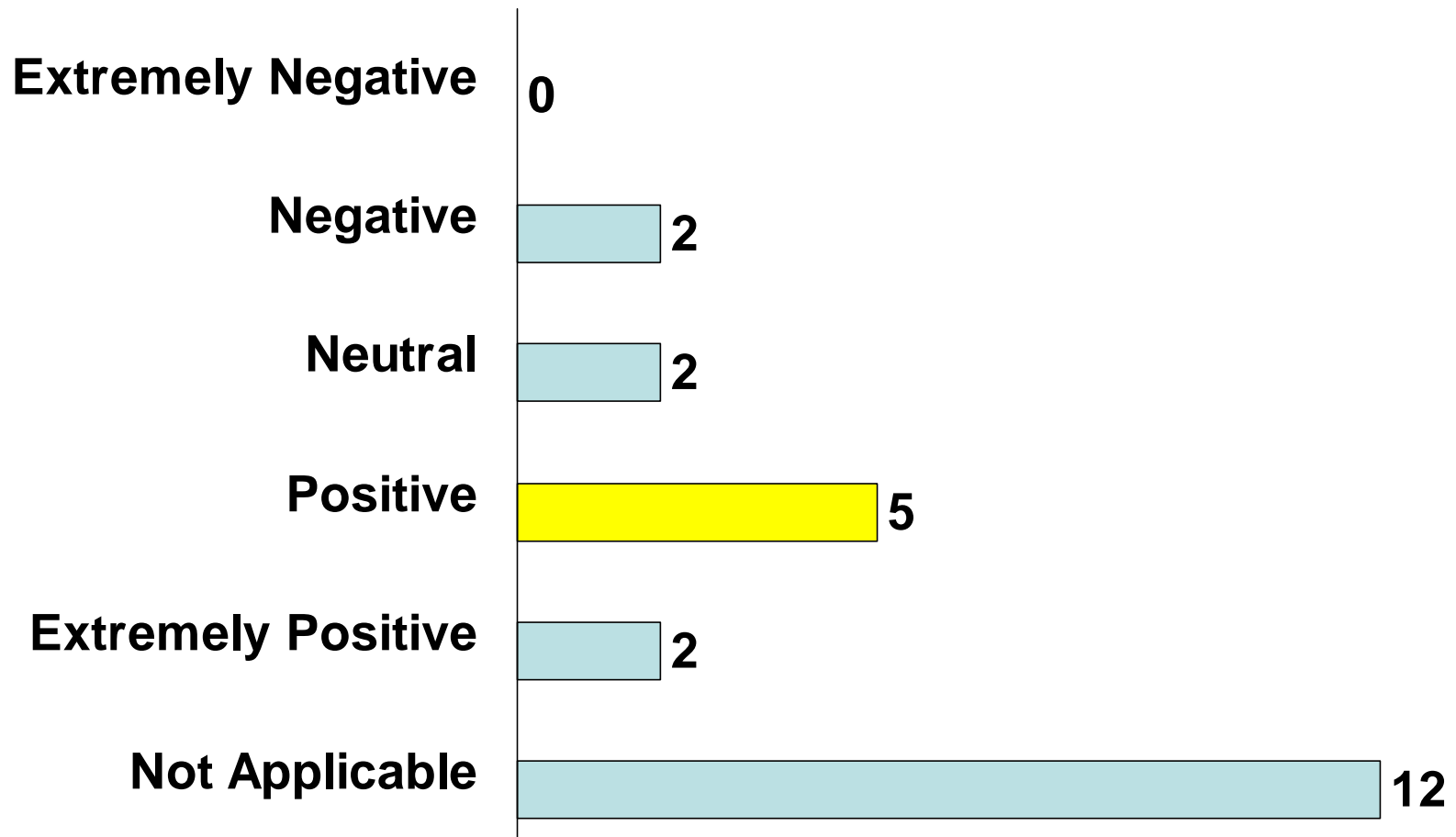
# How Often Third Party Reviewers Are Used for 510(k) Submissions



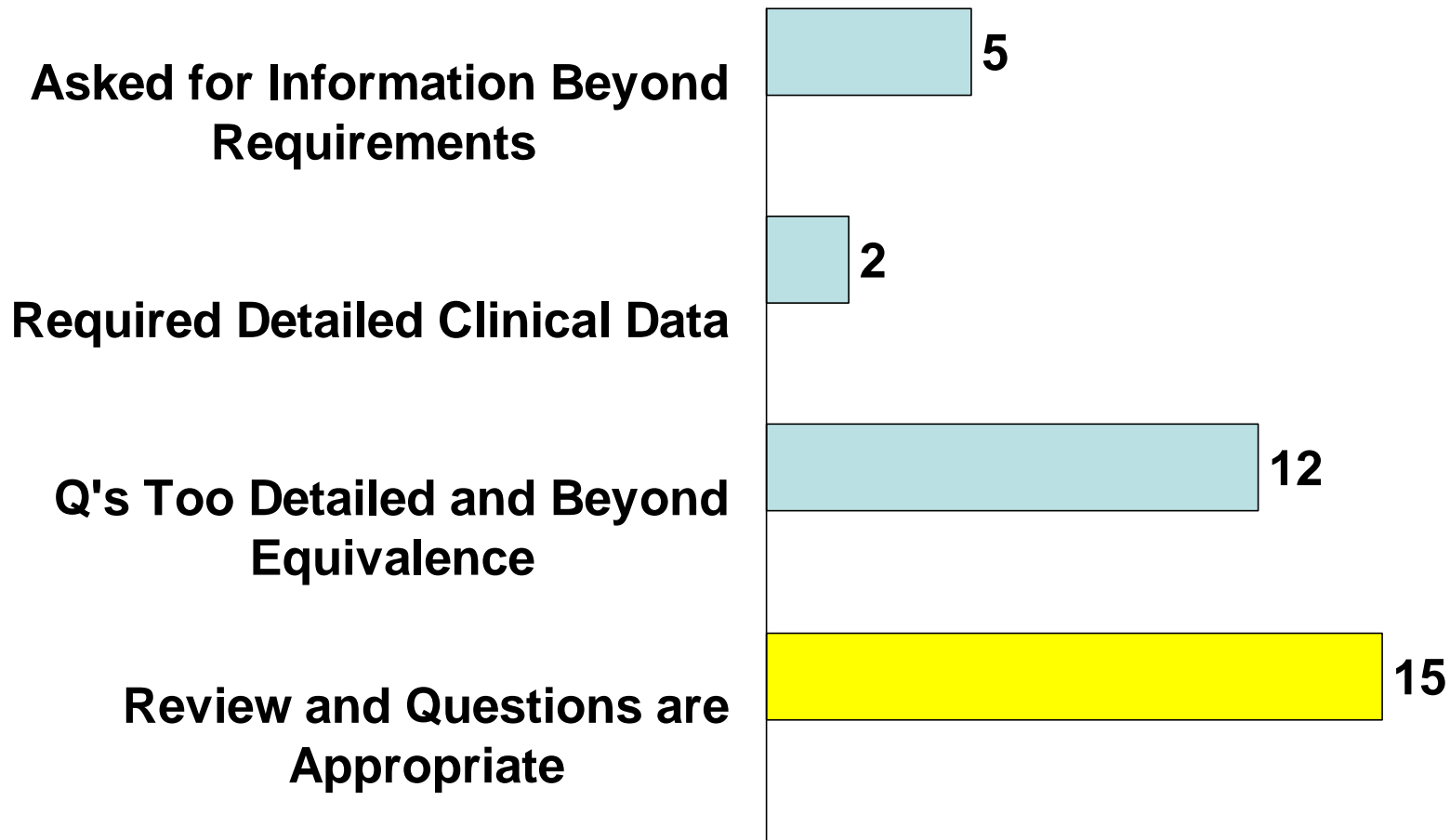
# Primary Reason for Using a Third Party Reviewer



# Experience Using a Third Party Reviewer

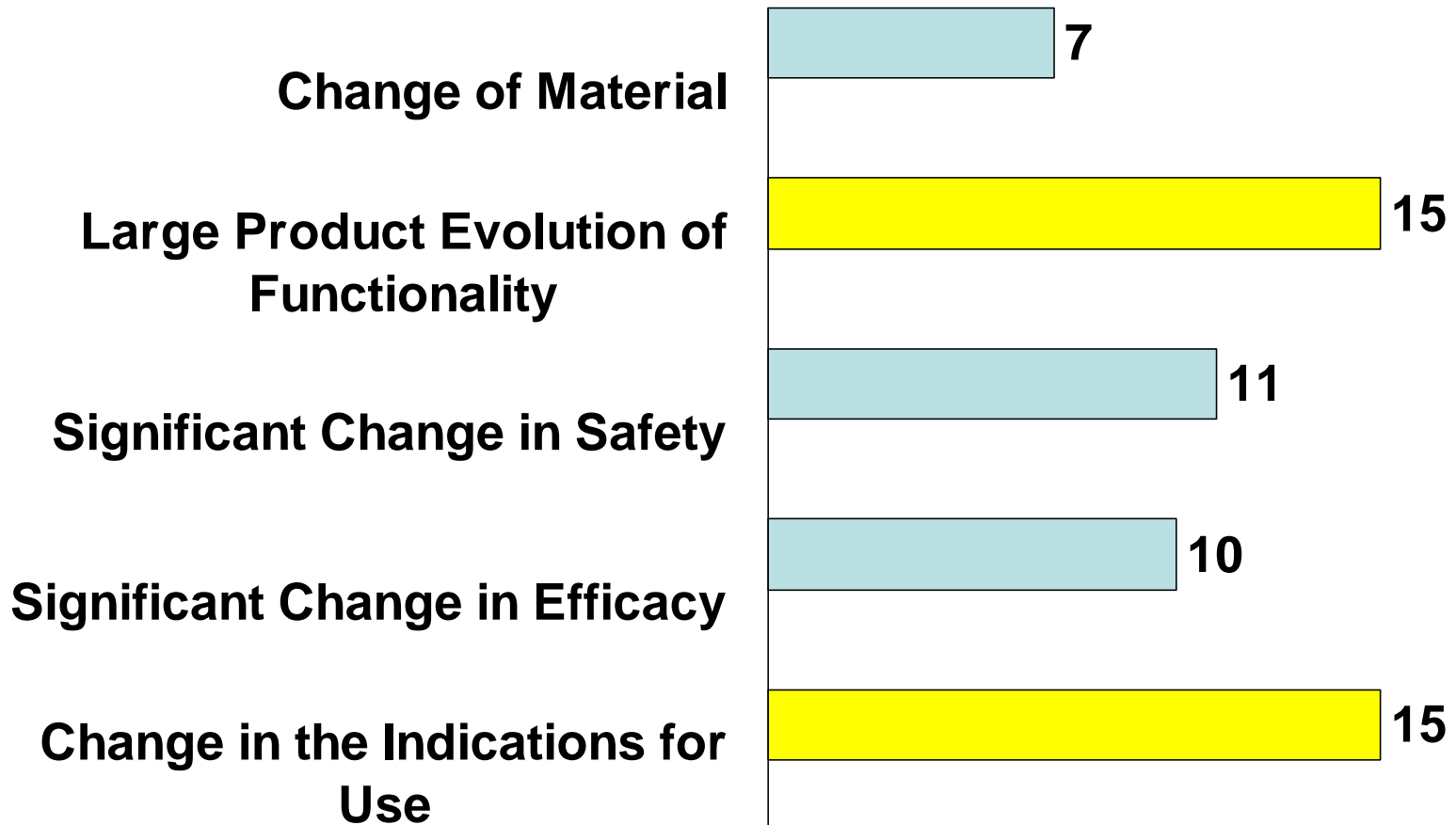


# Firms' Experience with FDA Review Process



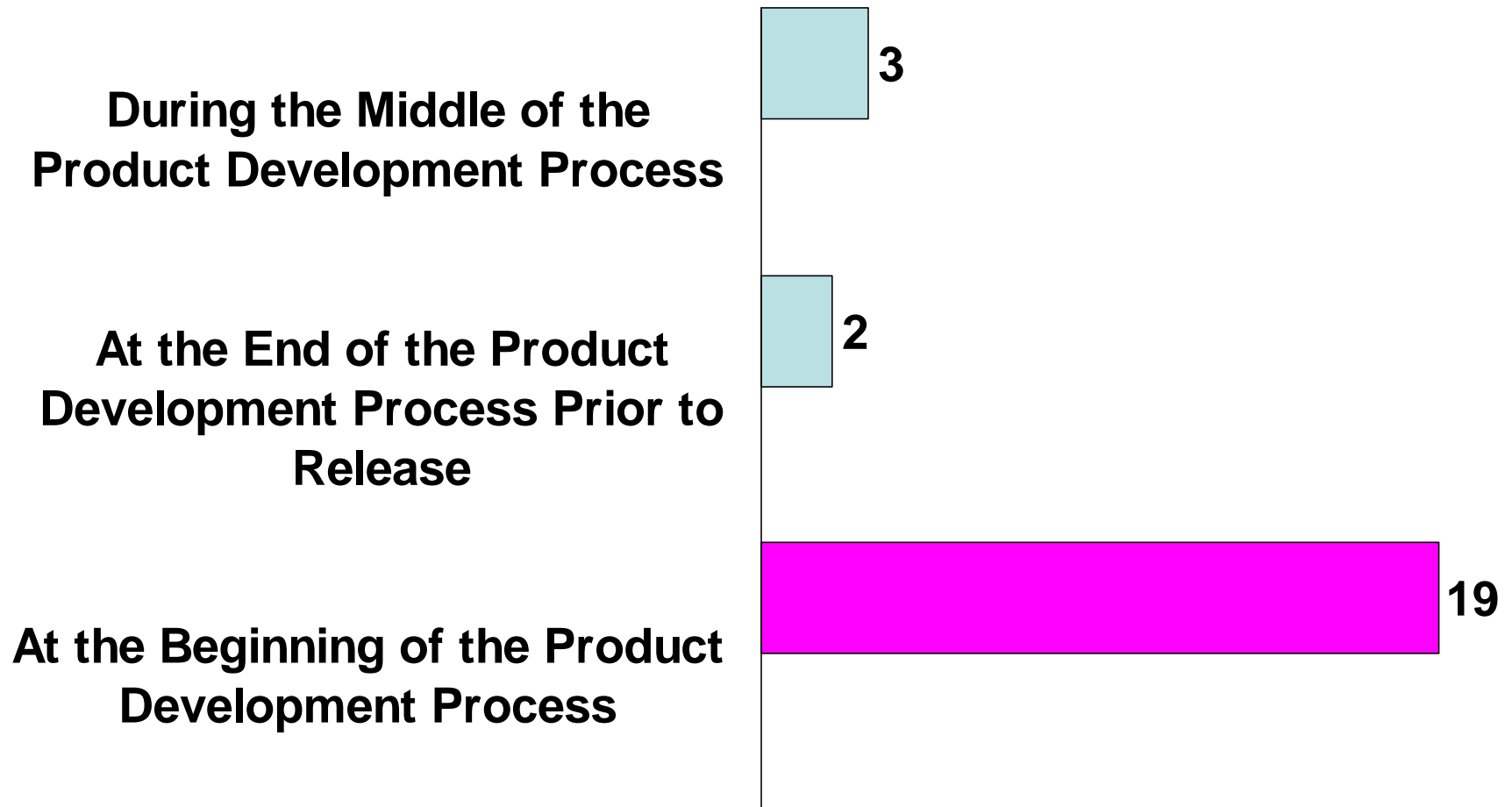
More than 1 answer chosen

# Circumstances When Firms Submitted a New 510(k) for a Device Modification

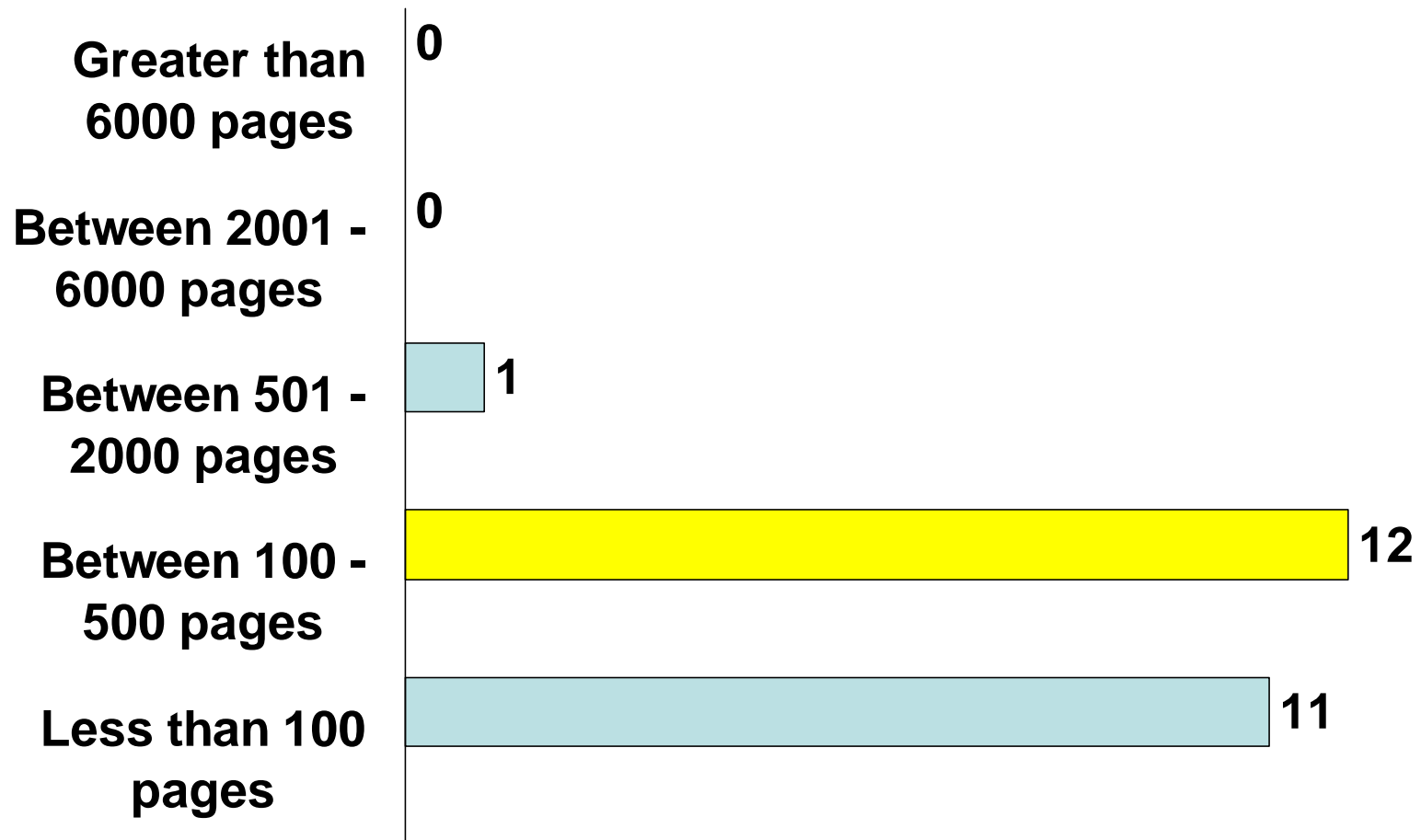


More than 1 answer chosen

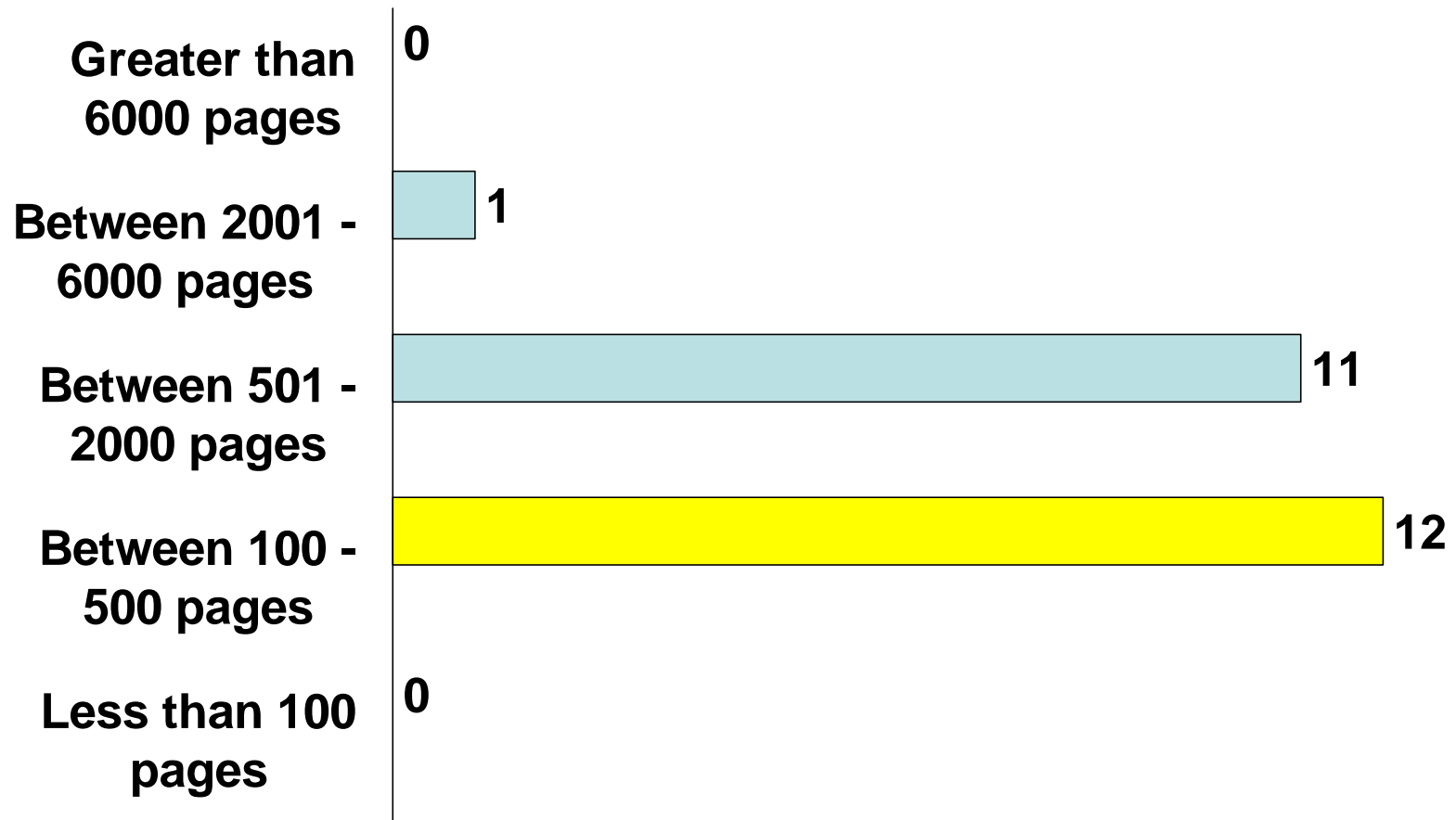
# When Firms Addressed the Need for a New 510(k) for New Product Releases



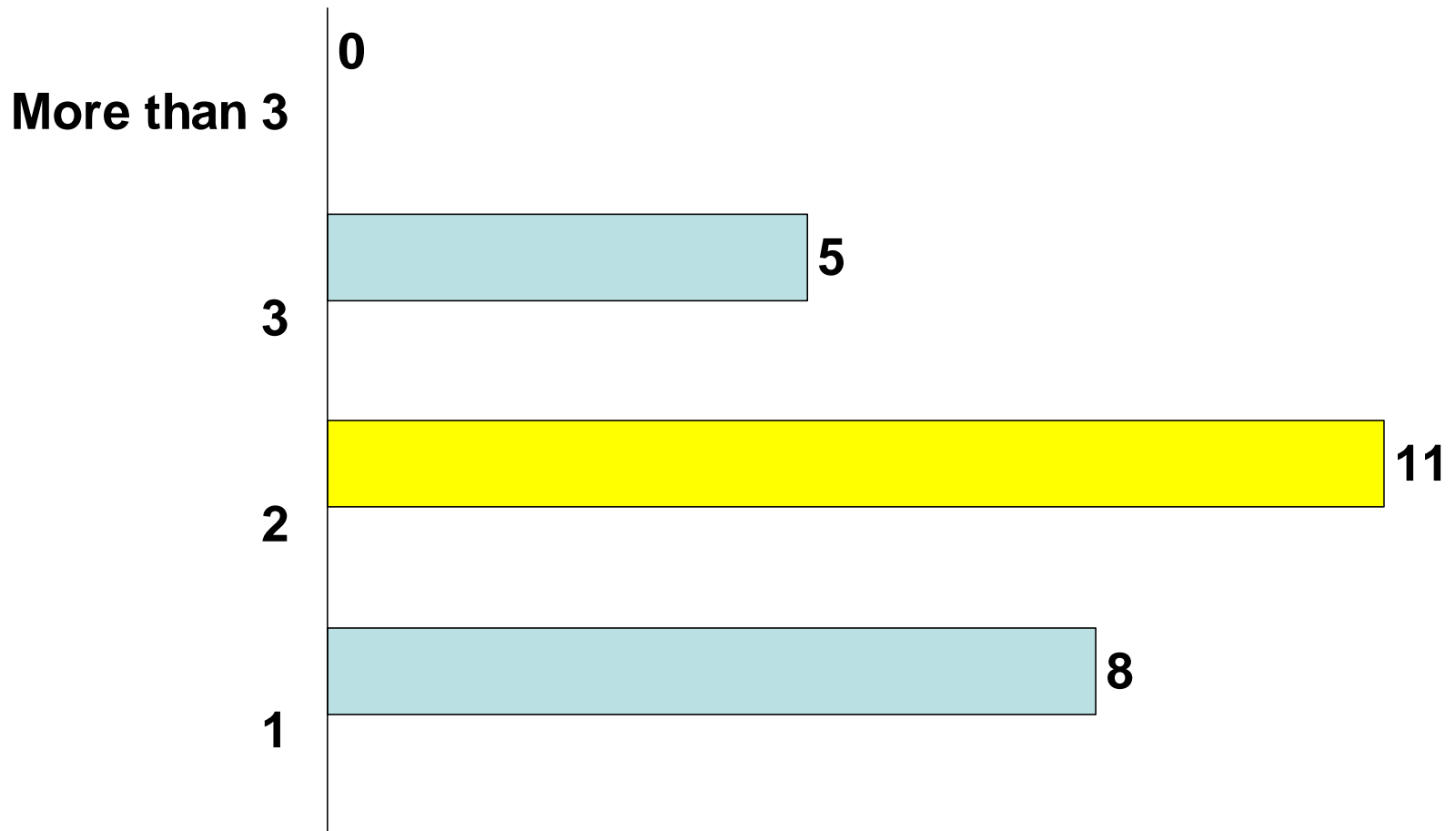
# Number of Pages for 510(k) for Least Complex Product Line



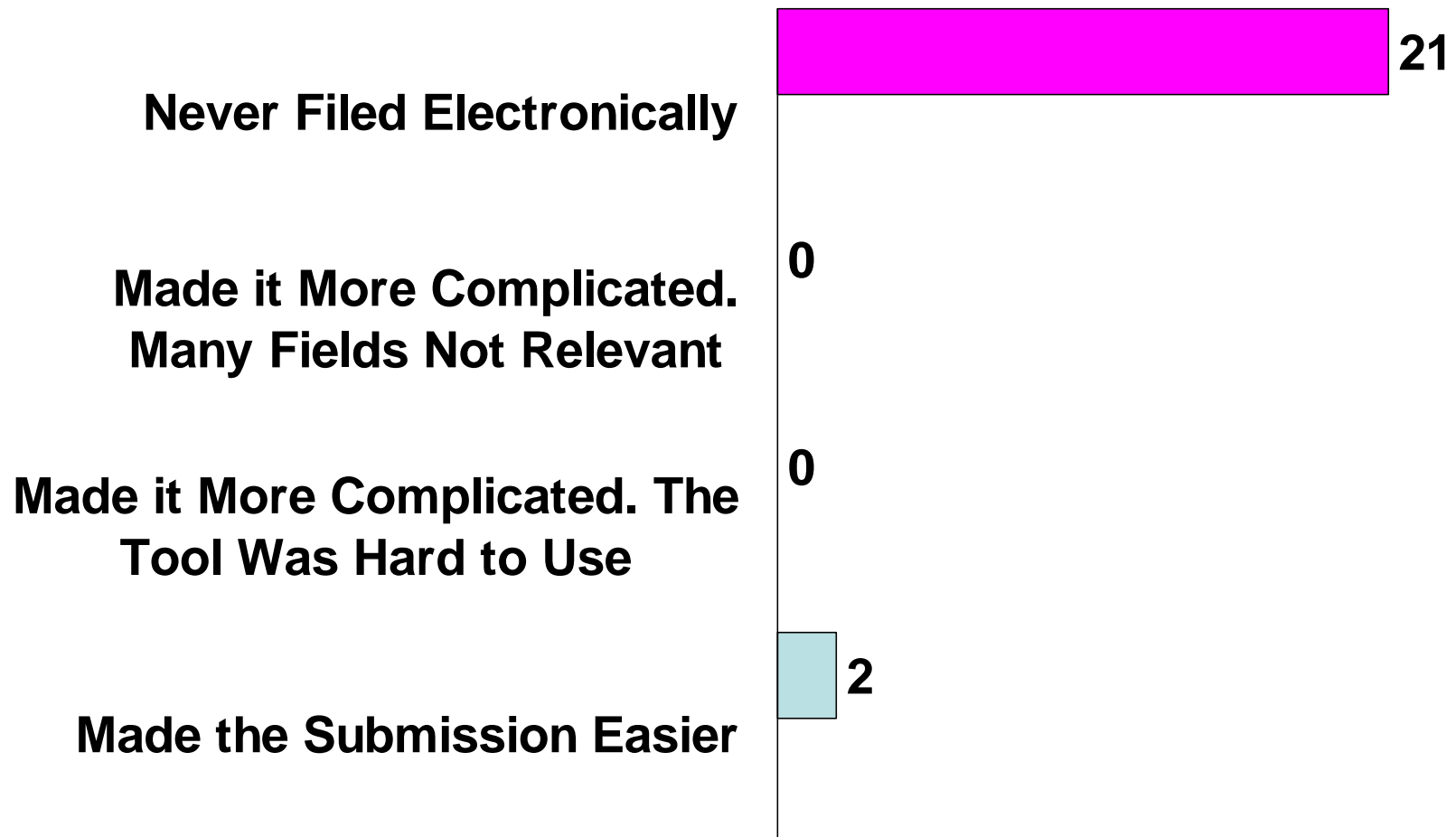
# Number of Pages for 510(k) for Most Complex Product Line



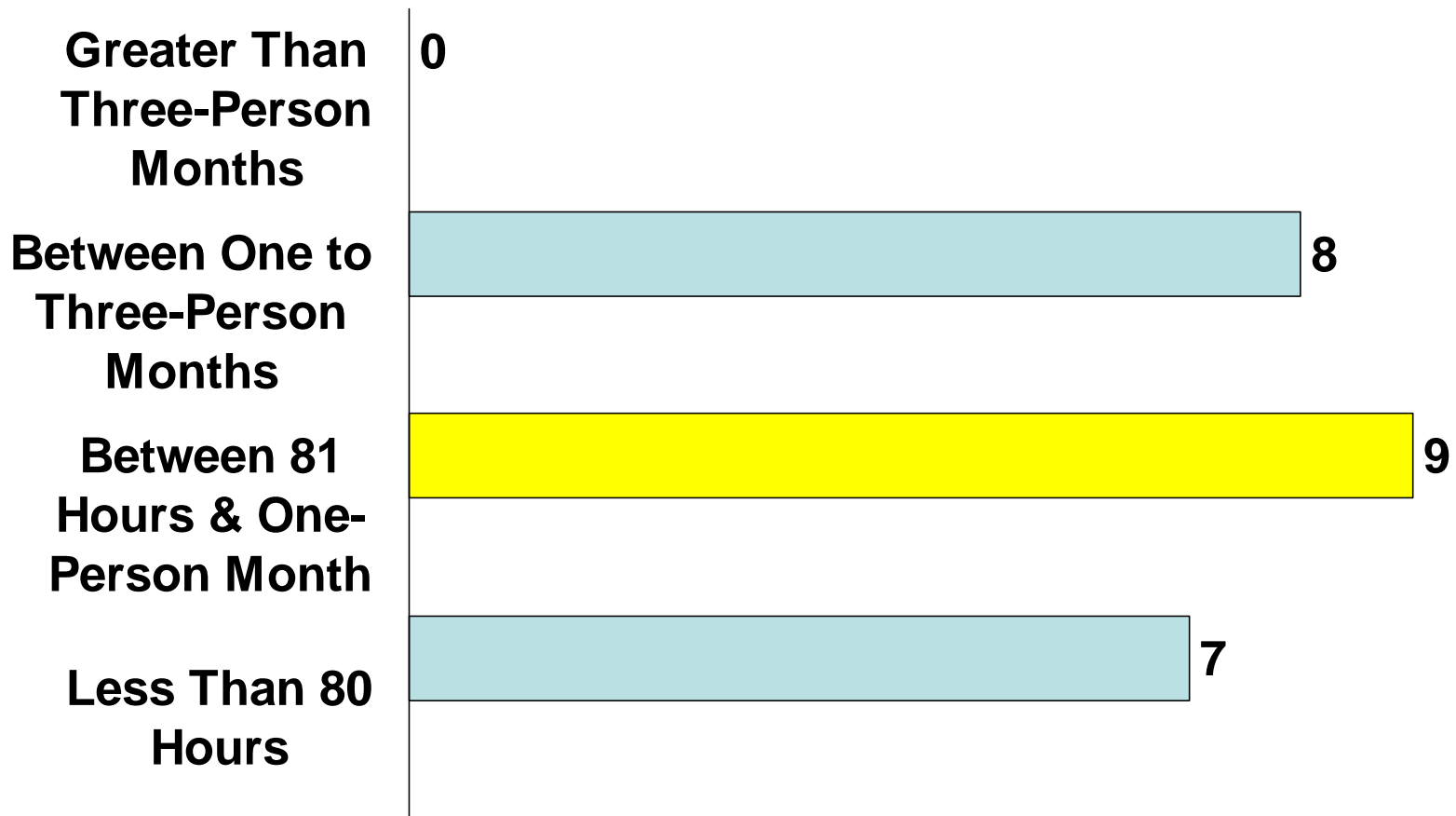
# Number of Predicate Devices Used for Comparison in 510(k)



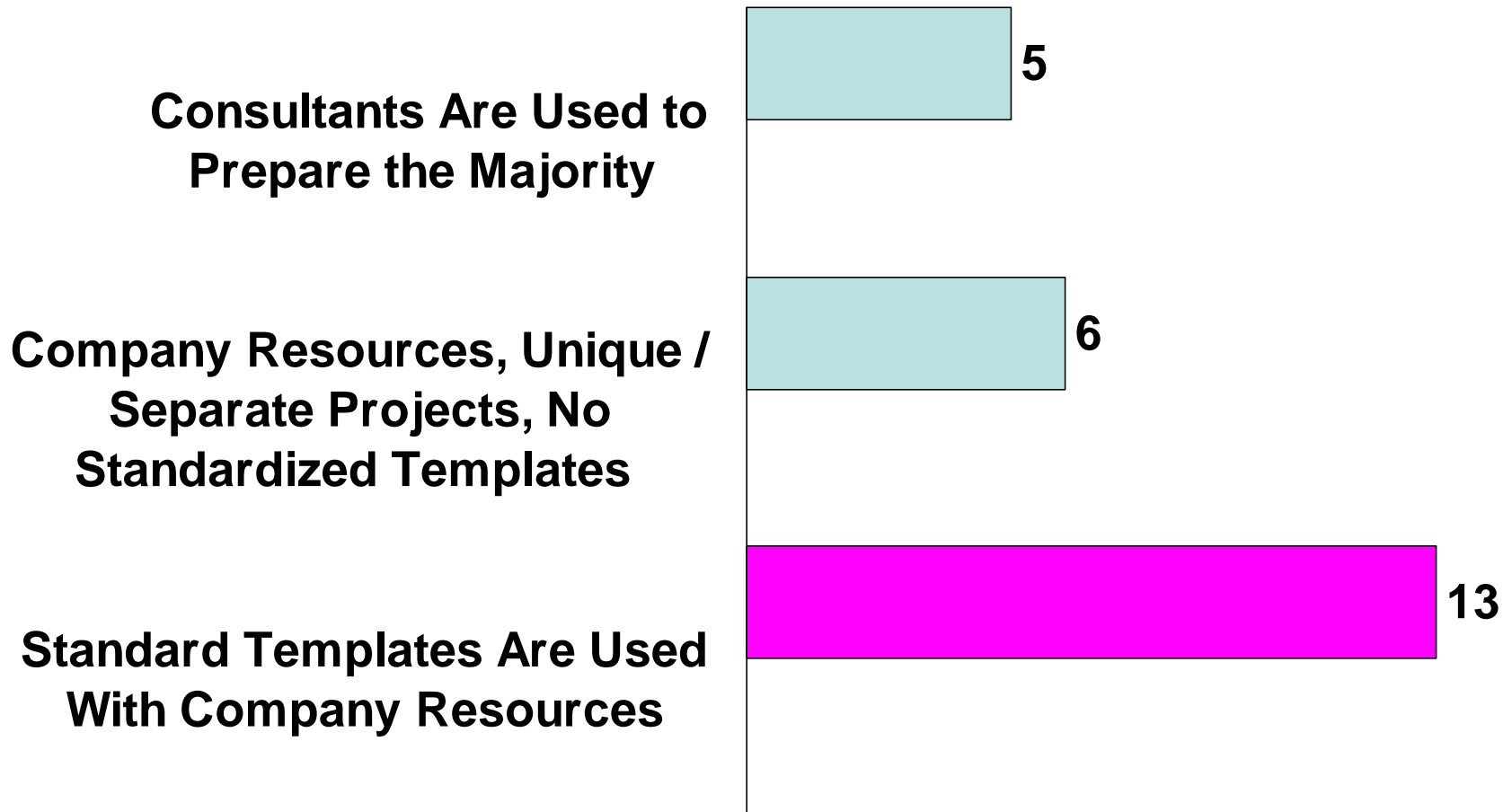
# Firms Using FDA's Automated Tools for Electronic Submission of a 510(k)



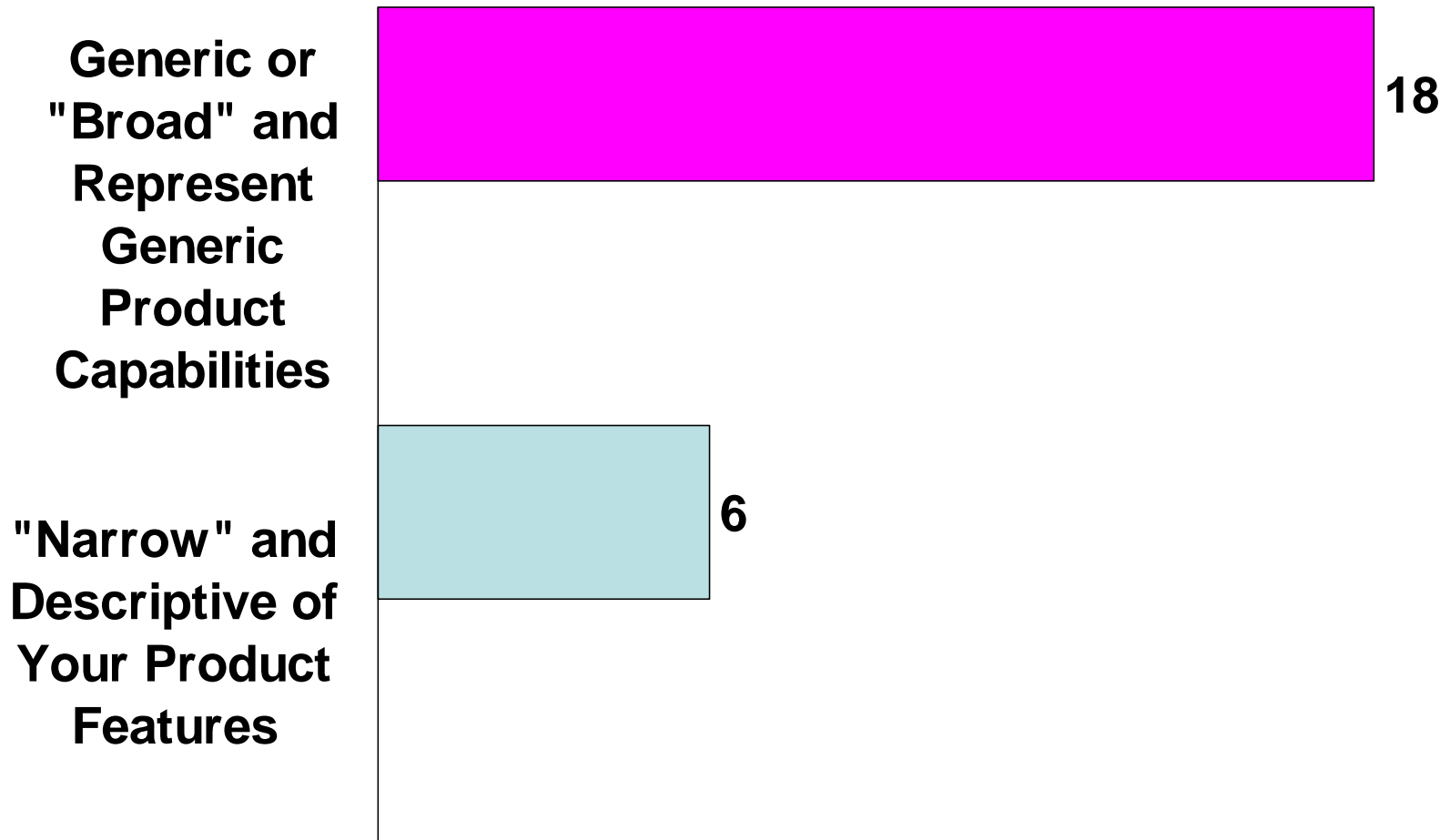
# Effort/Time Required to Prepare a 510(k) and Support Responses to Questions



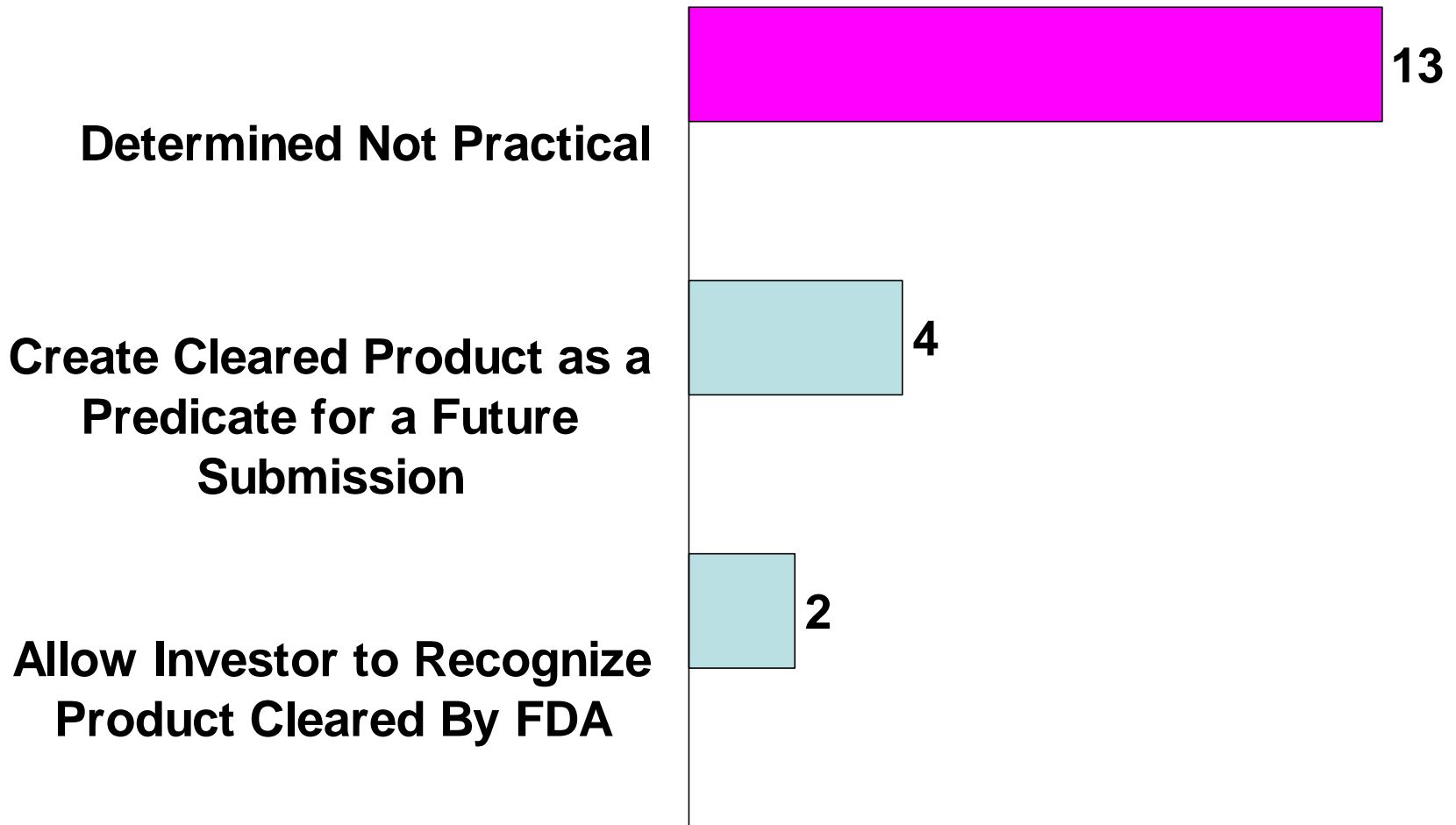
# How Firms Prepared their 510(k) Submissions



# Approach to Defining the 510(k)s' Indication for Use



# Reason that Product Subject to 510(k) Submission Was Not Marketed



# How FDA 510(k) Process Compares With Clearance Used By Other Countries (CE Mark, etc...)

