

510(k) Benchmarking Survey

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



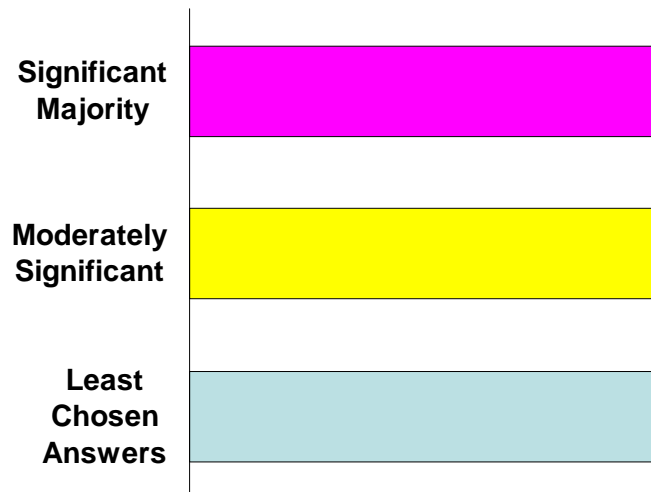
Dan Olivier
Certified Compliance Solutions
certifiedcompliance.com
doliver@certifiedcompliance.com



Demographics

- Survey conducted June 2008
- 235 respondents
- Large, medium and small firms were represented

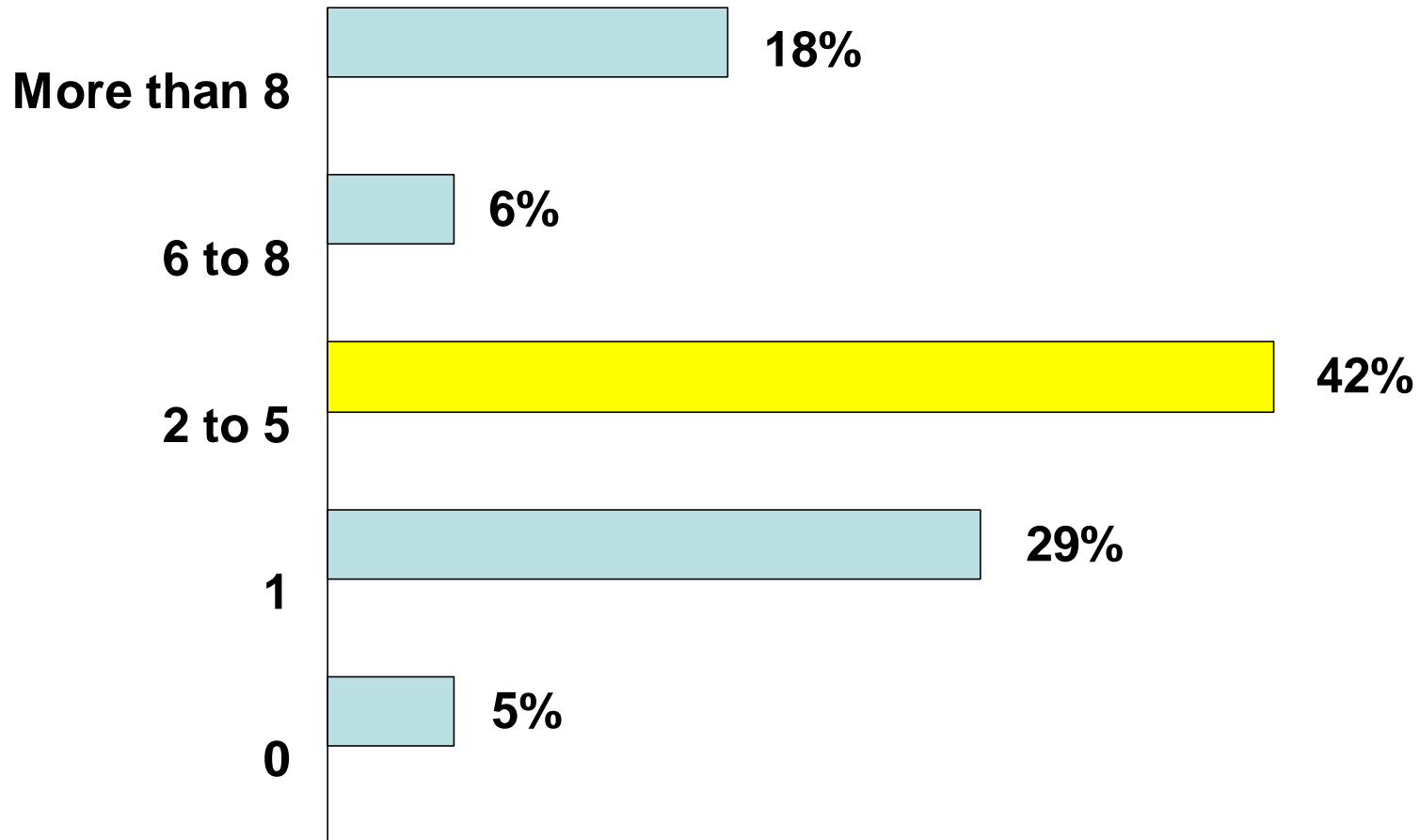
Color Legend



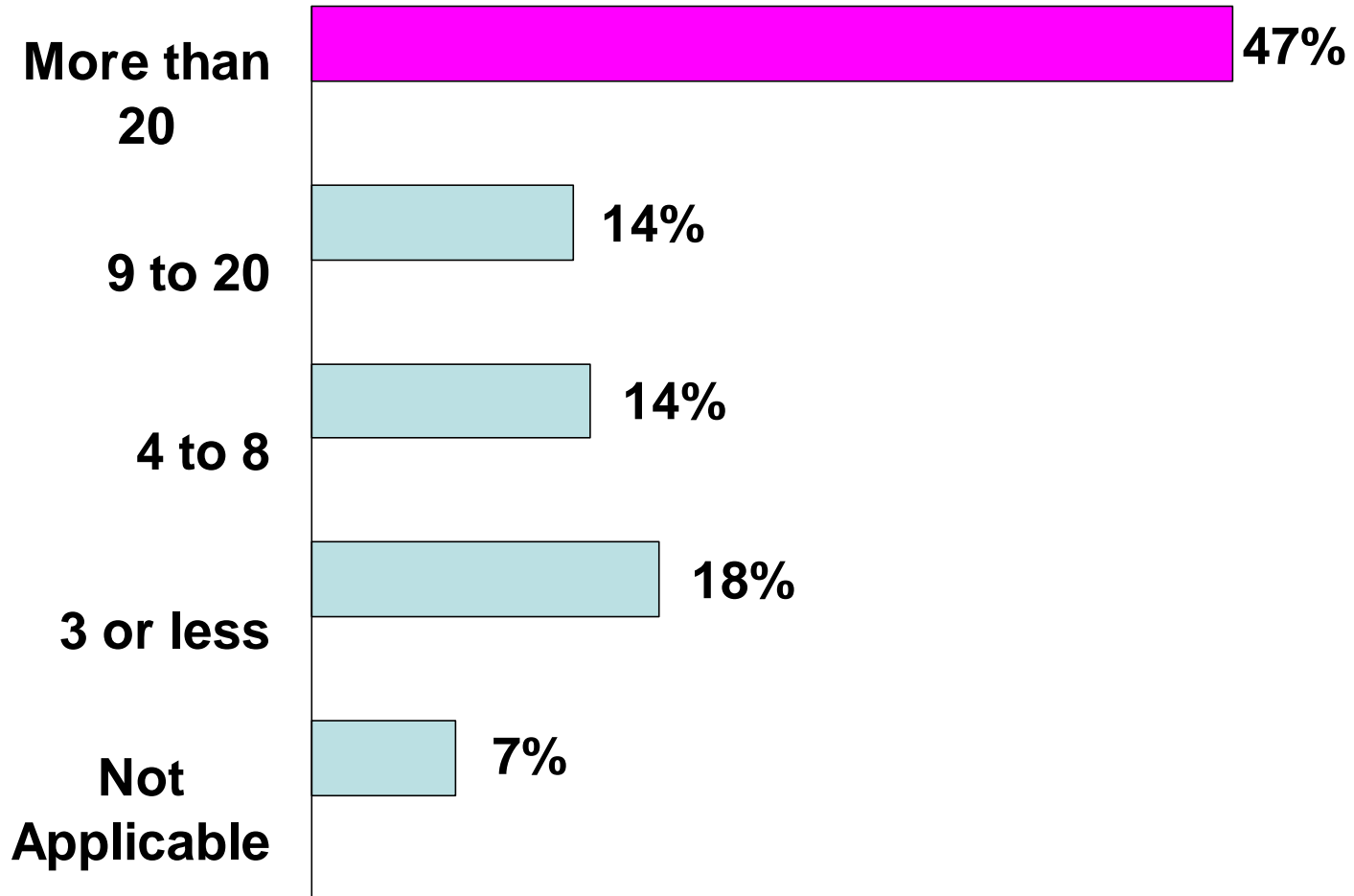
Product Categories

Products Categories	Number of Firms Making that Category of Products
Anesthesiology devices	28
Cardiovascular devices	62
Clinical chemistry devices	20
Dental devices	19
Ear nose and throat devices	15
Gastroenterology-urology devices	24
General and plastic surgery devices	39
General hospital and personal use devices	51
Hematology and pathology devices	20
IVDs	62
Neurological devices	22
Obstetrical and gynecological devices	21
Ophthalmic devices	18
Orthopedic devices	31
Physical medicine devices	9
Radiological devices	45
Other	25

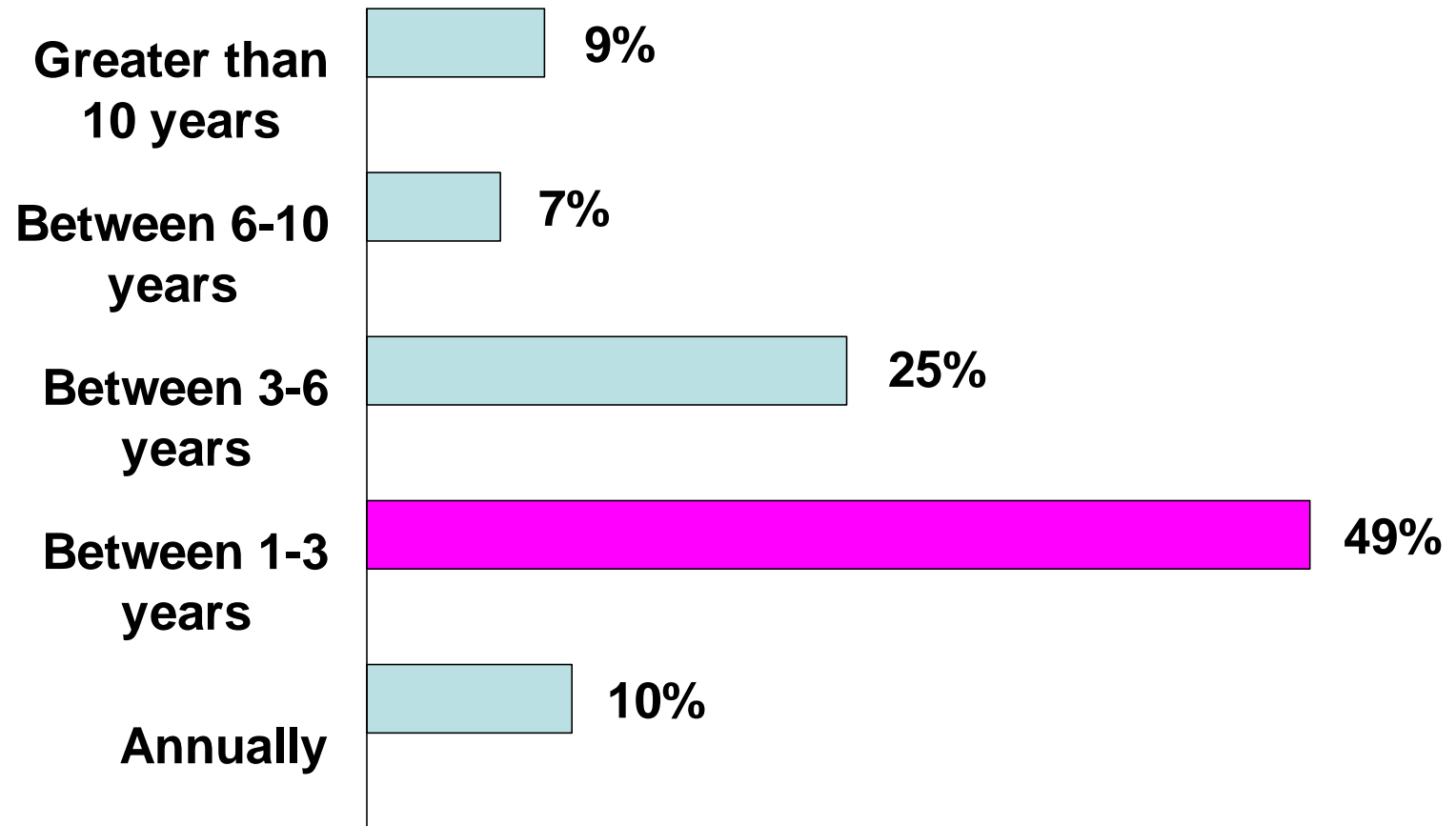
Number of 510(k)s Submitted Annually



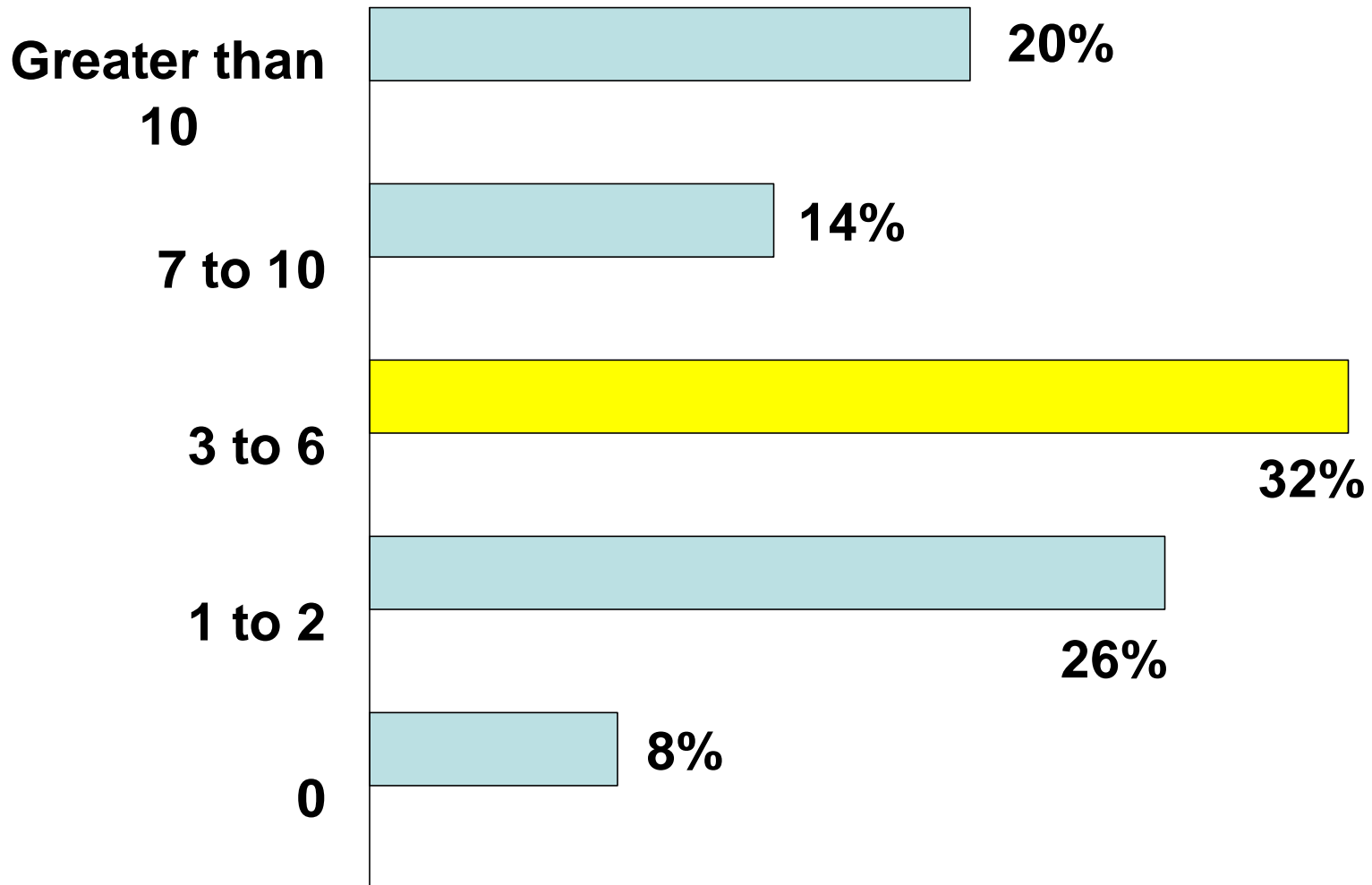
Number of 510(k)s Cleared



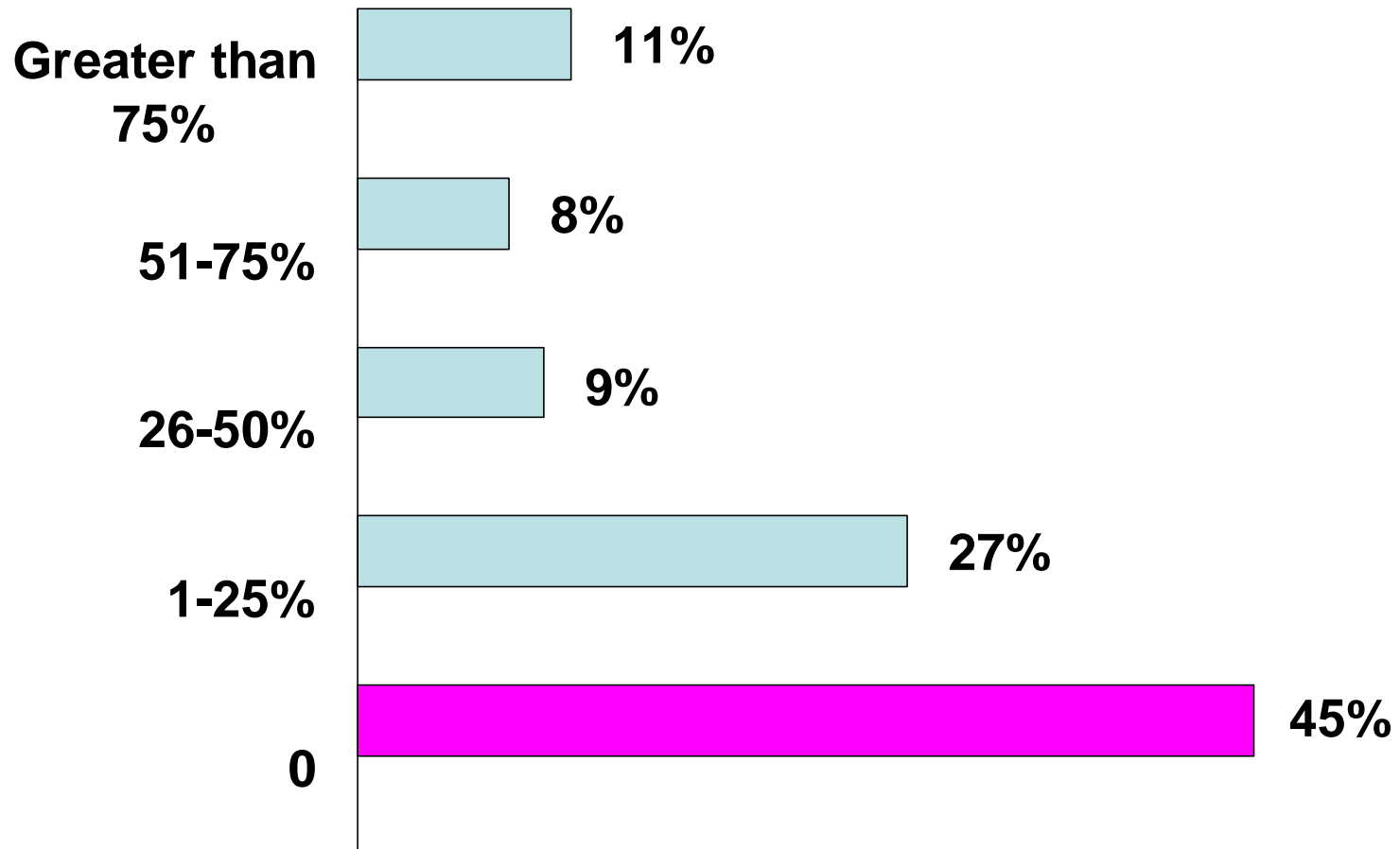
How Often Firms Submitted 510(k)s for Changes to their Products



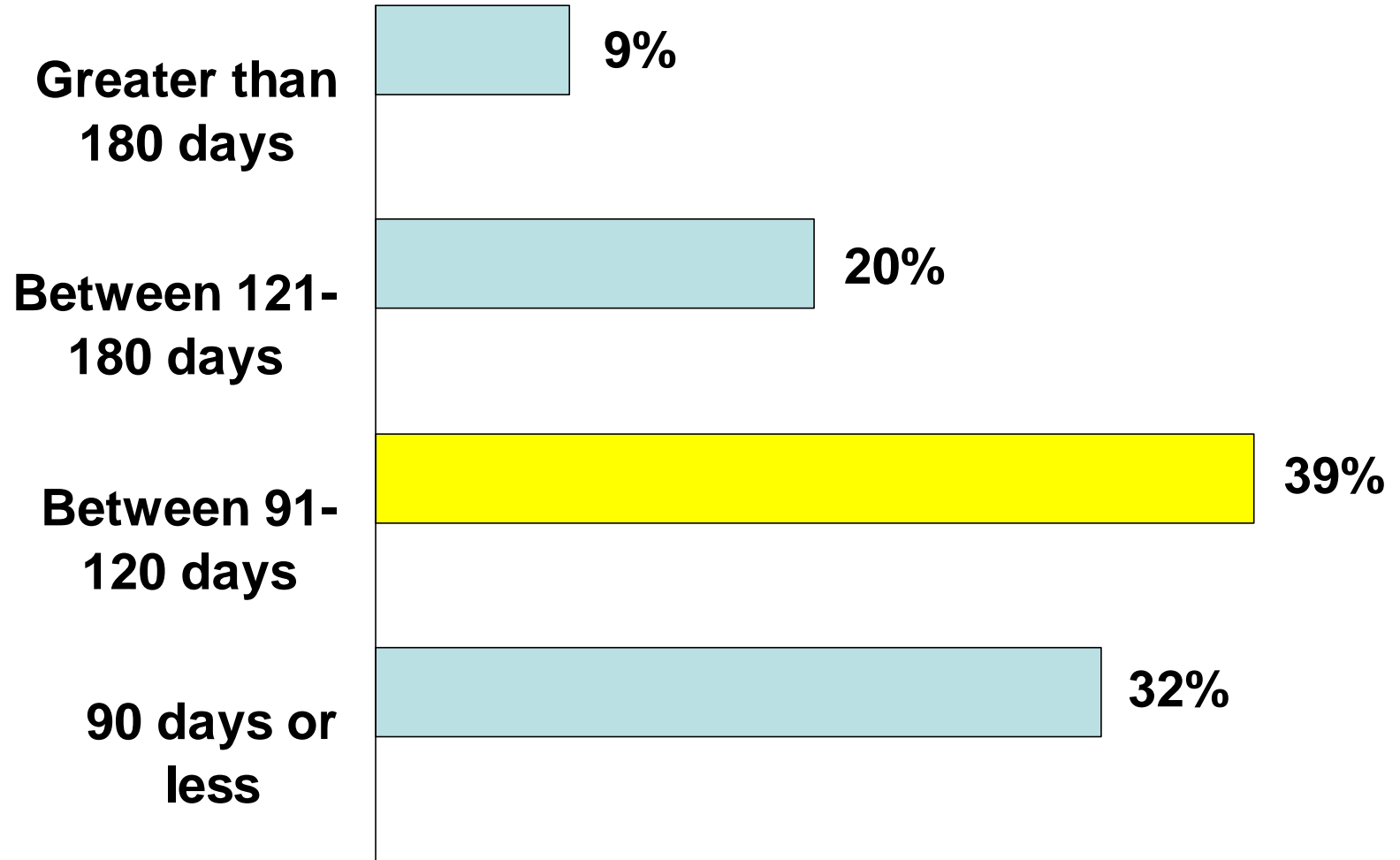
Number of Submissions in the Last 3 Years



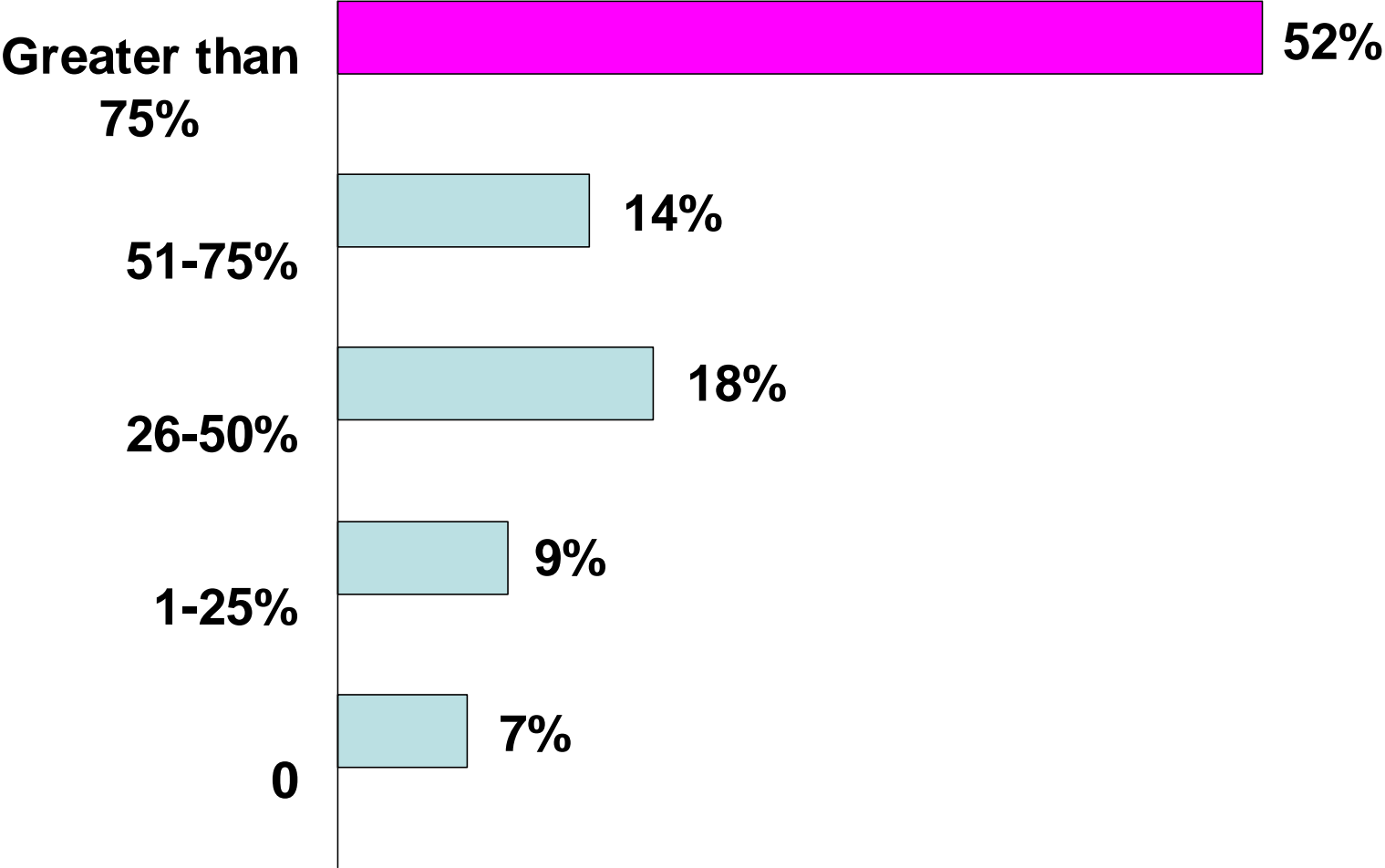
Percent of Submissions Where FDA Didn't Ask for Additional Data



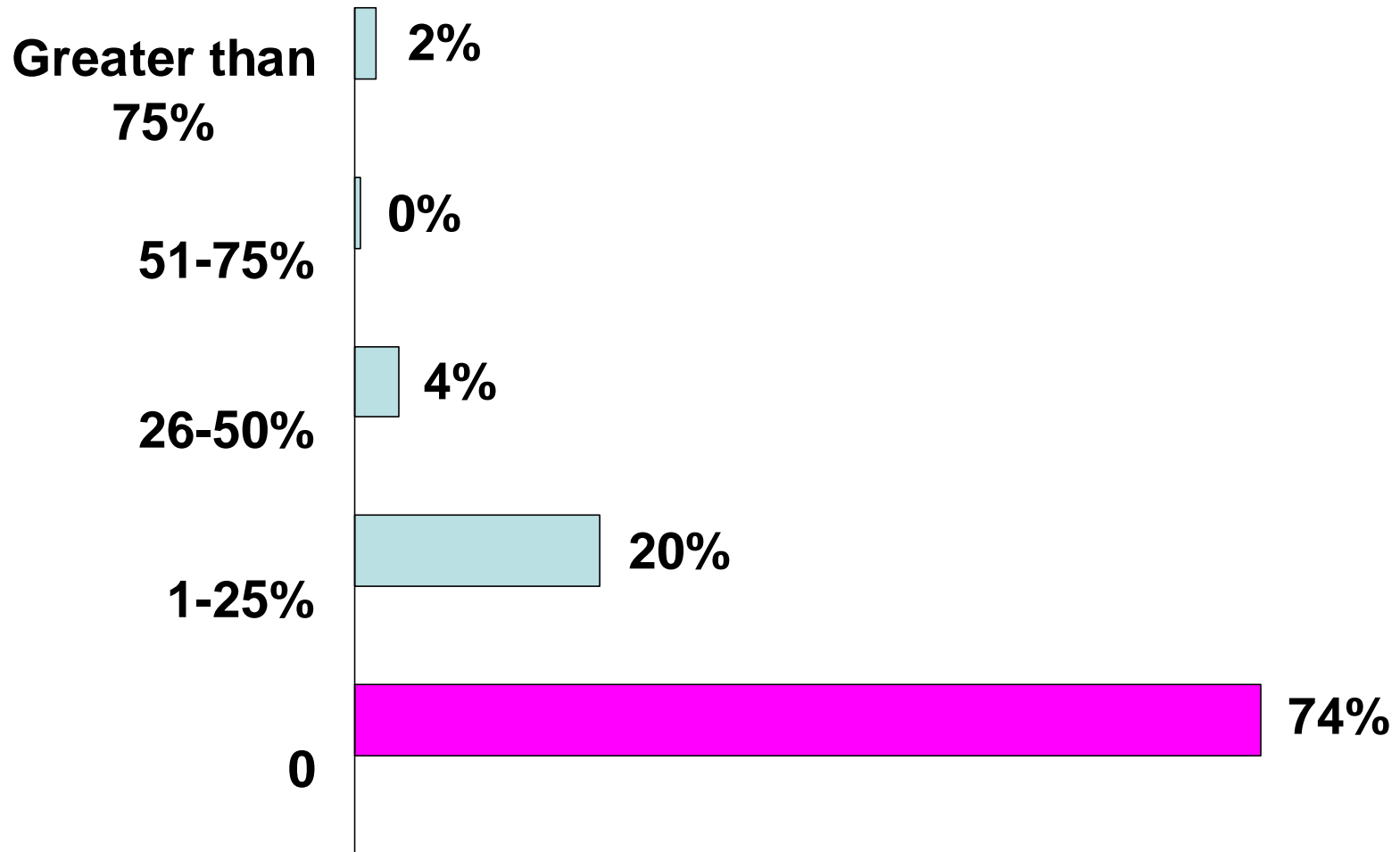
Time from 510(k) Submission to Receiving a Clearance



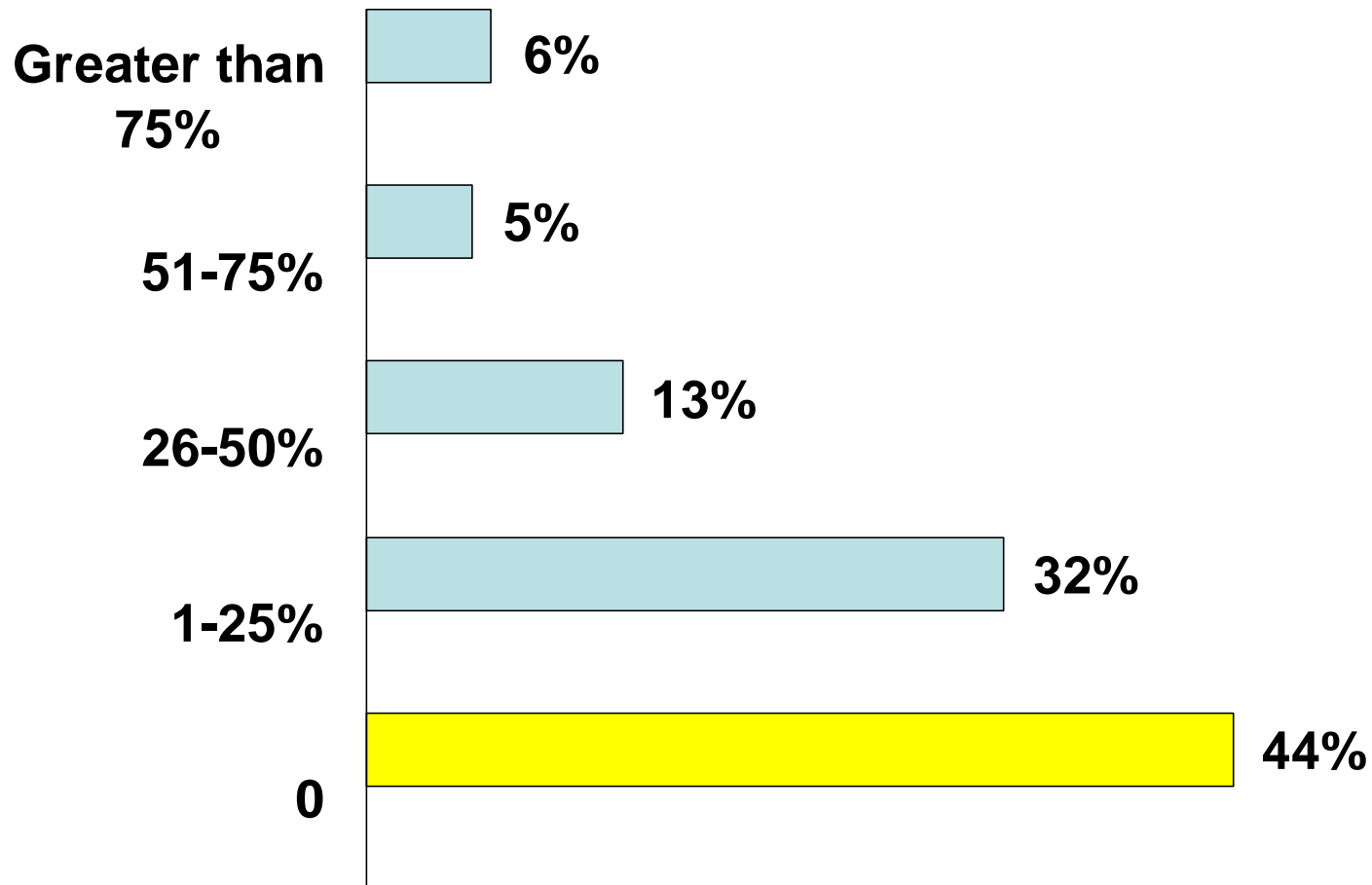
In the past 3 years, the percentage of 510(k) submissions that were “Traditional”



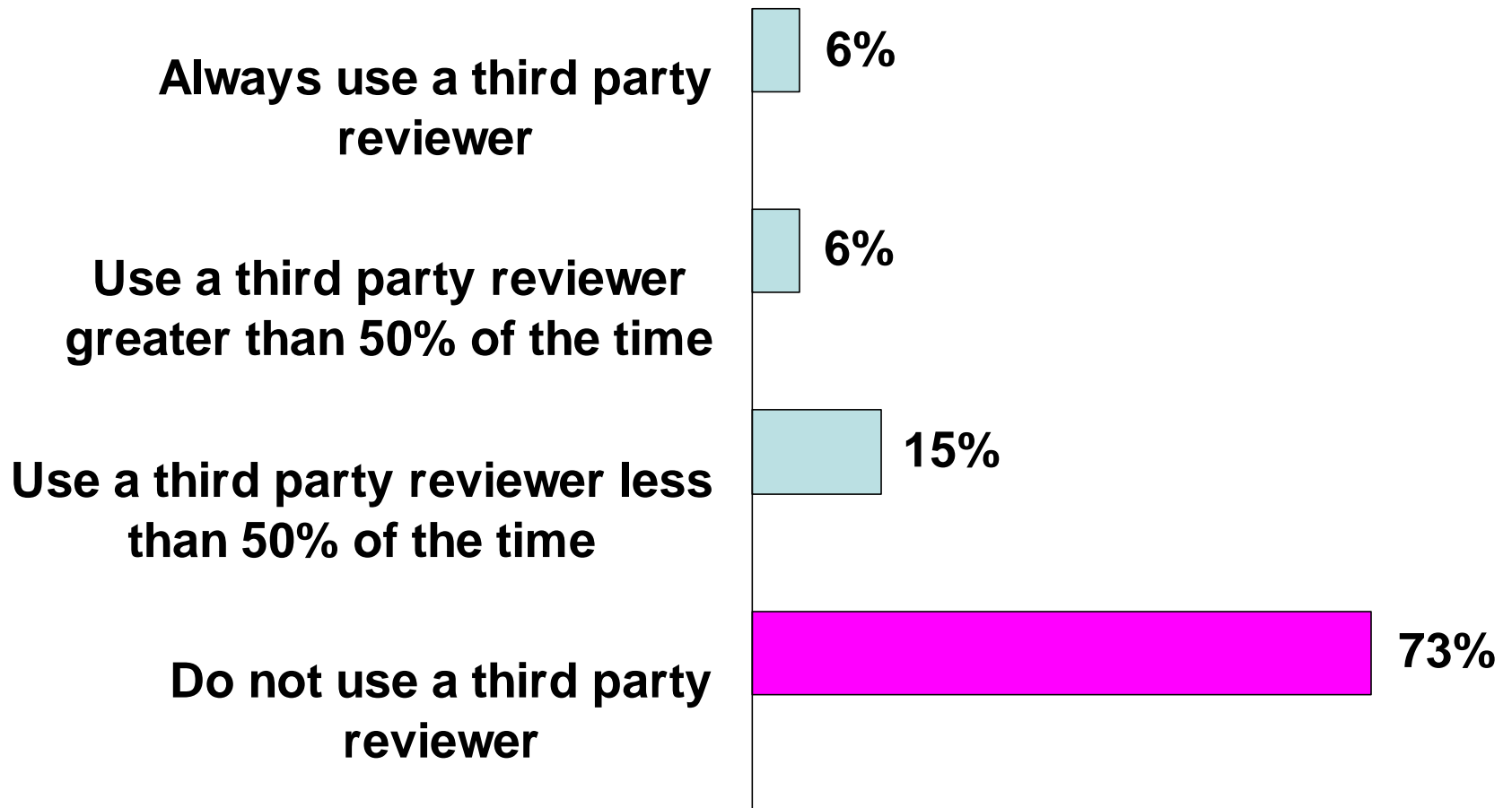
In the past 3 years, the percentage of 510(k) submissions that were “Abbreviated”



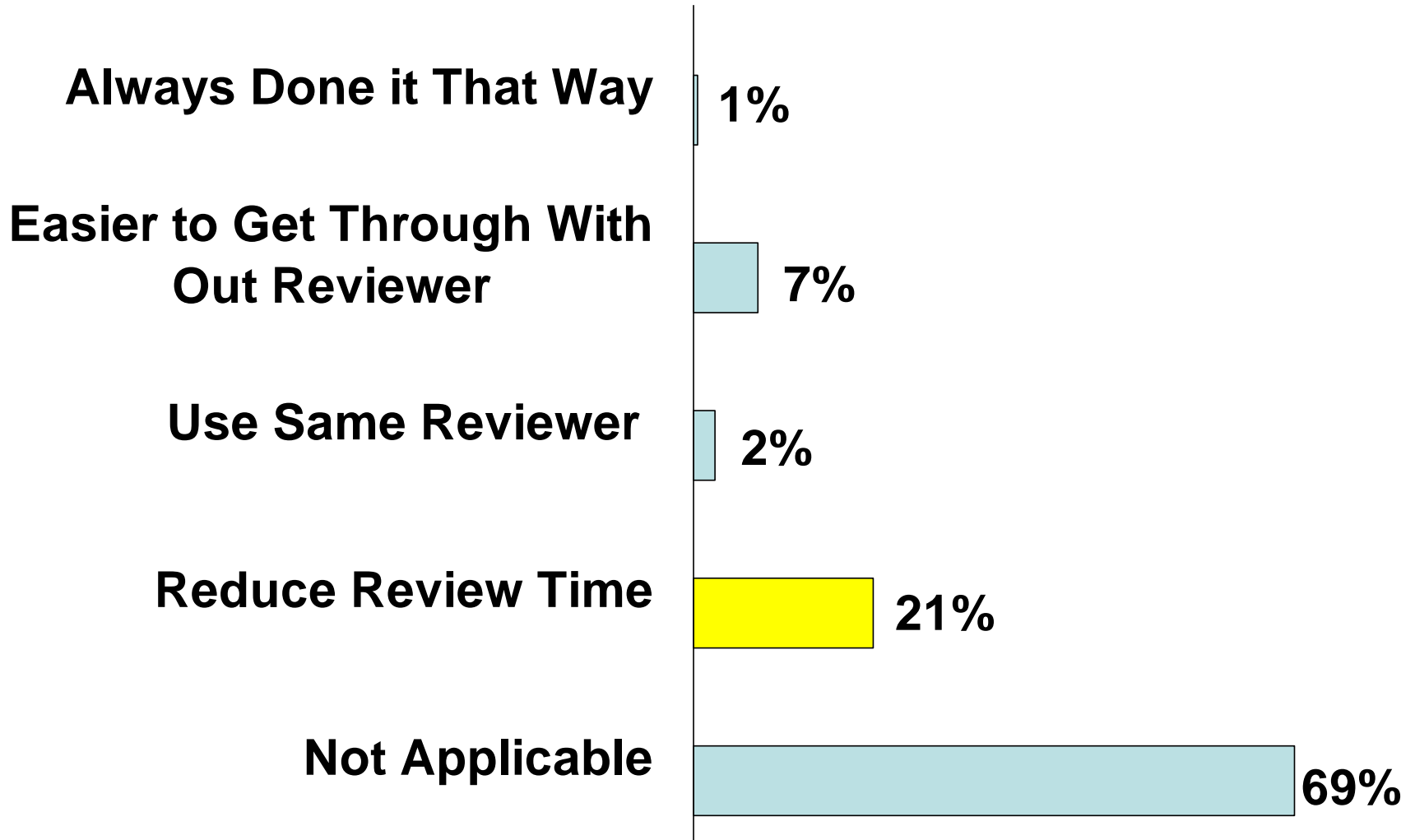
In the past 3 years, the percentage of 510(k) submissions that were “Special”



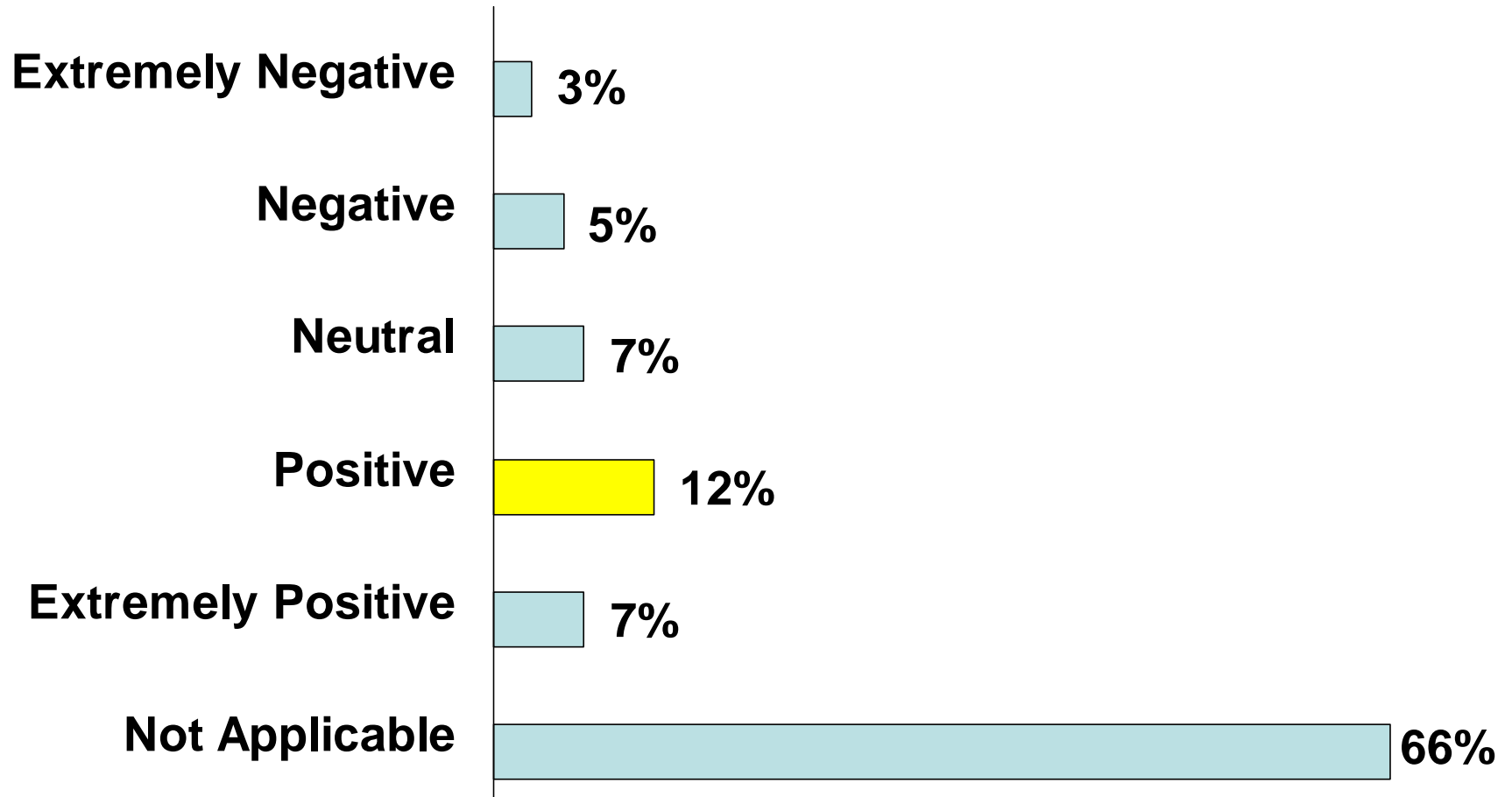
How Often Third Party Reviewers Are Used for 510(k) Submissions



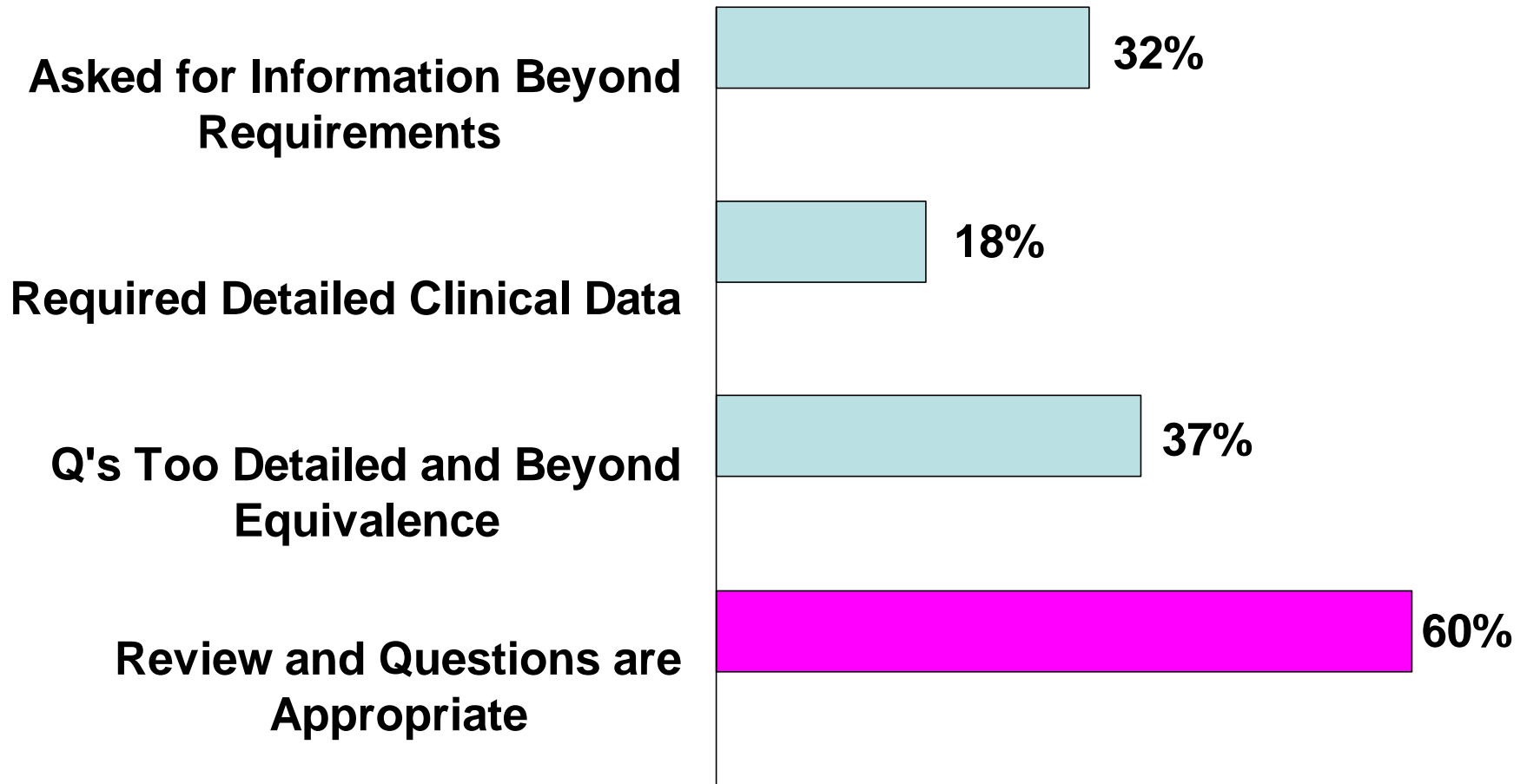
Primary Reason for Using a Third Party Reviewer



Experience Using a Third Party Reviewer

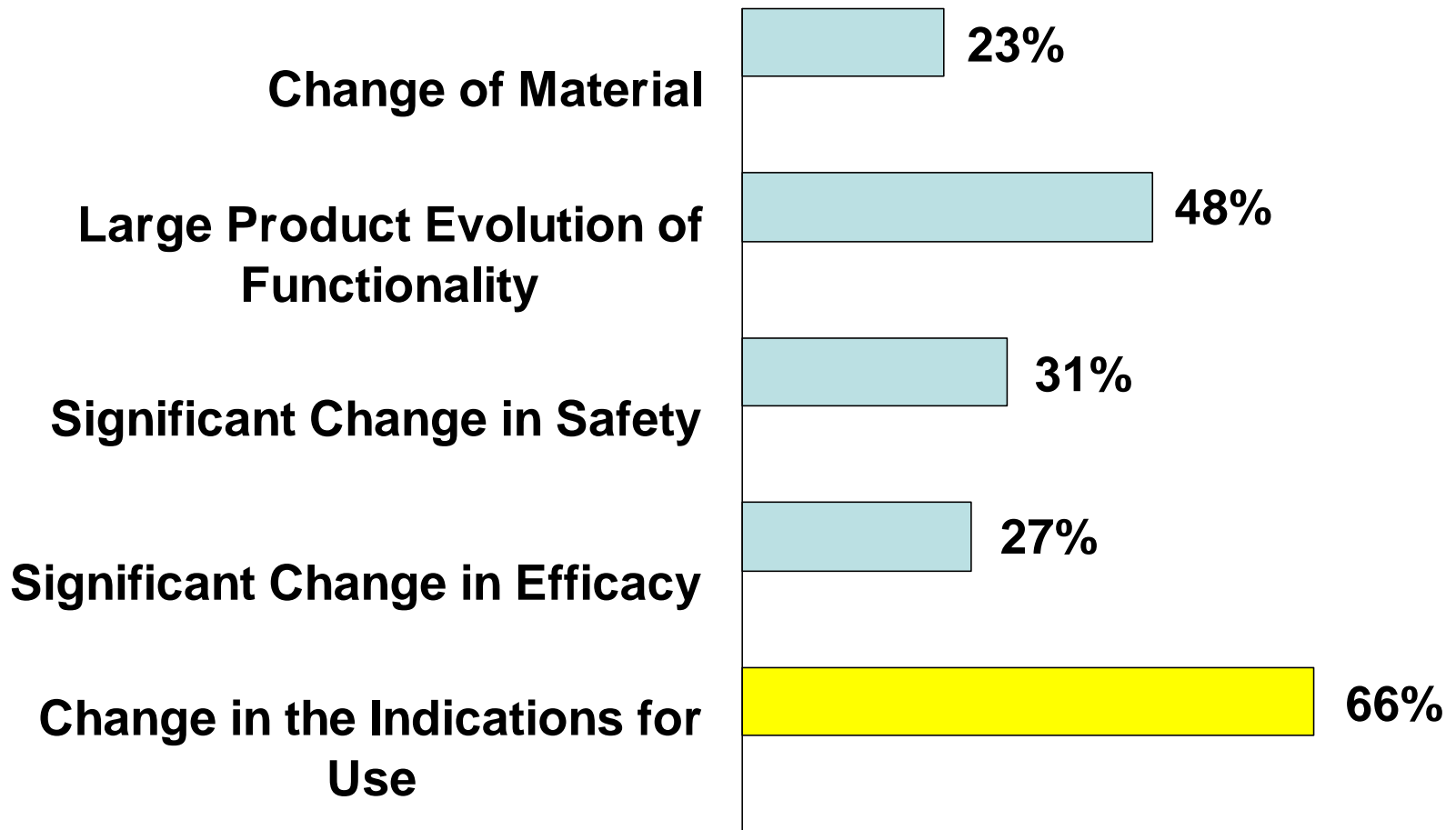


Firms' Experience with FDA Review Process



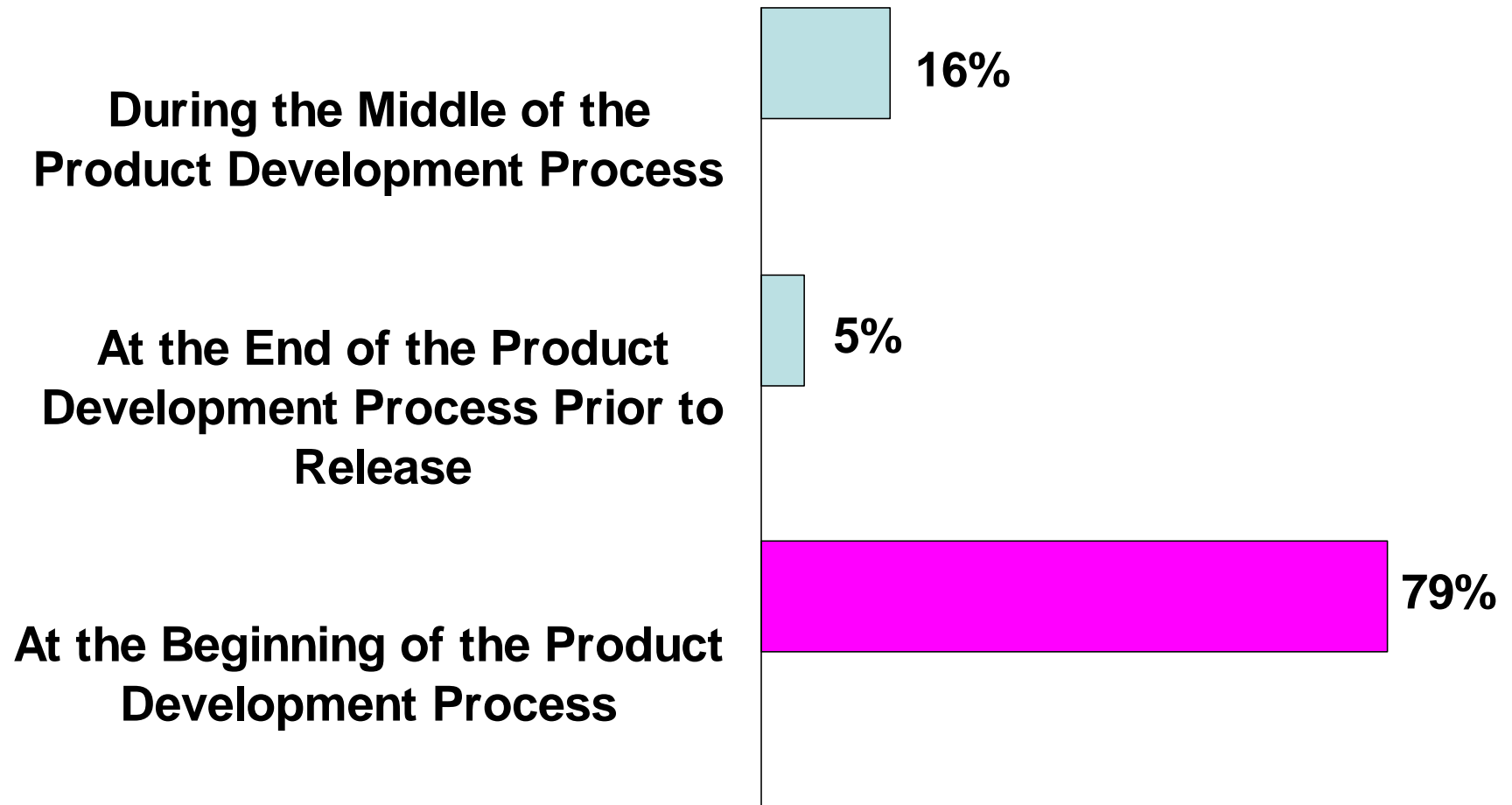
More than 1 answer chosen

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

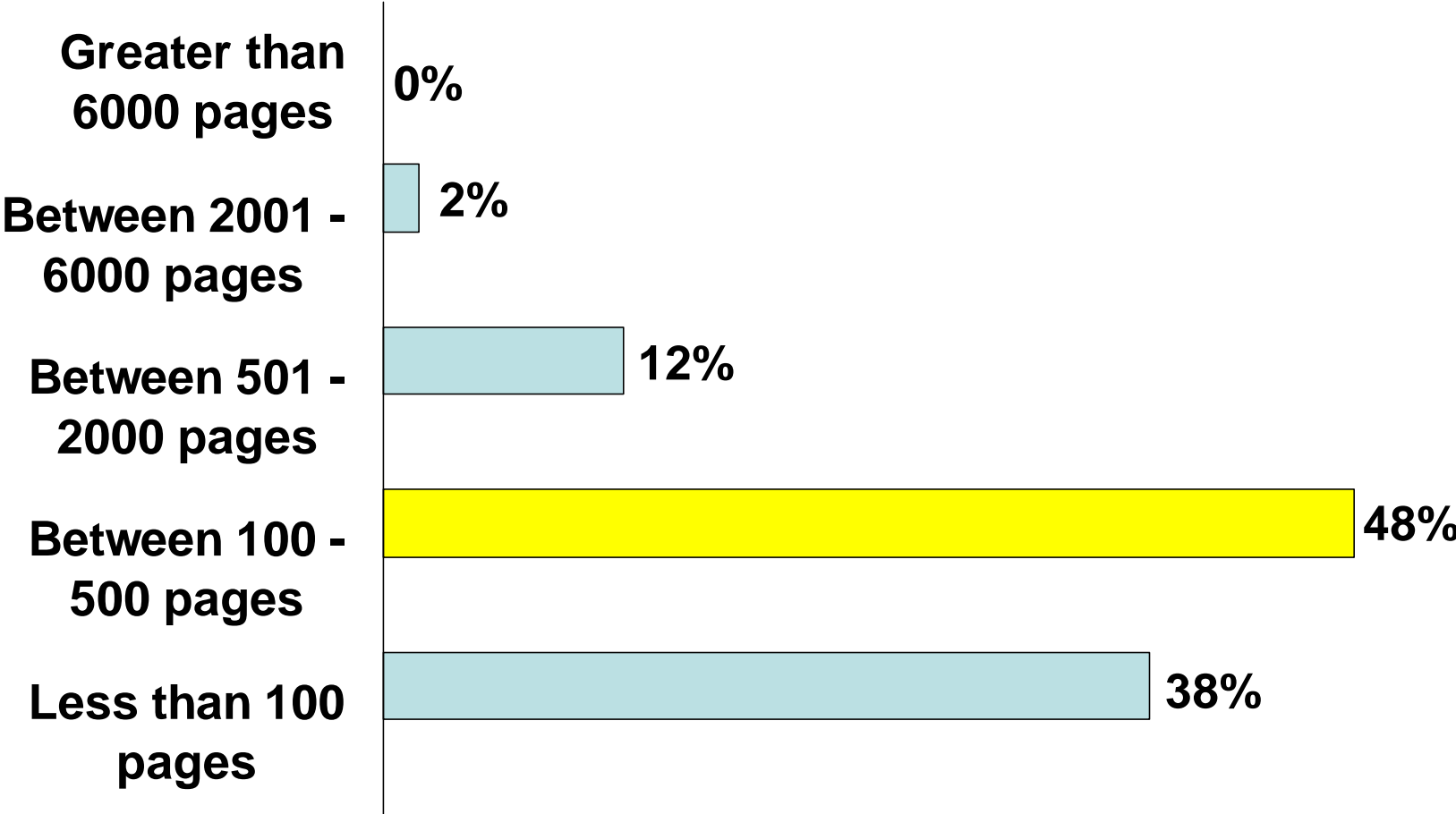


More than 1 answer chosen

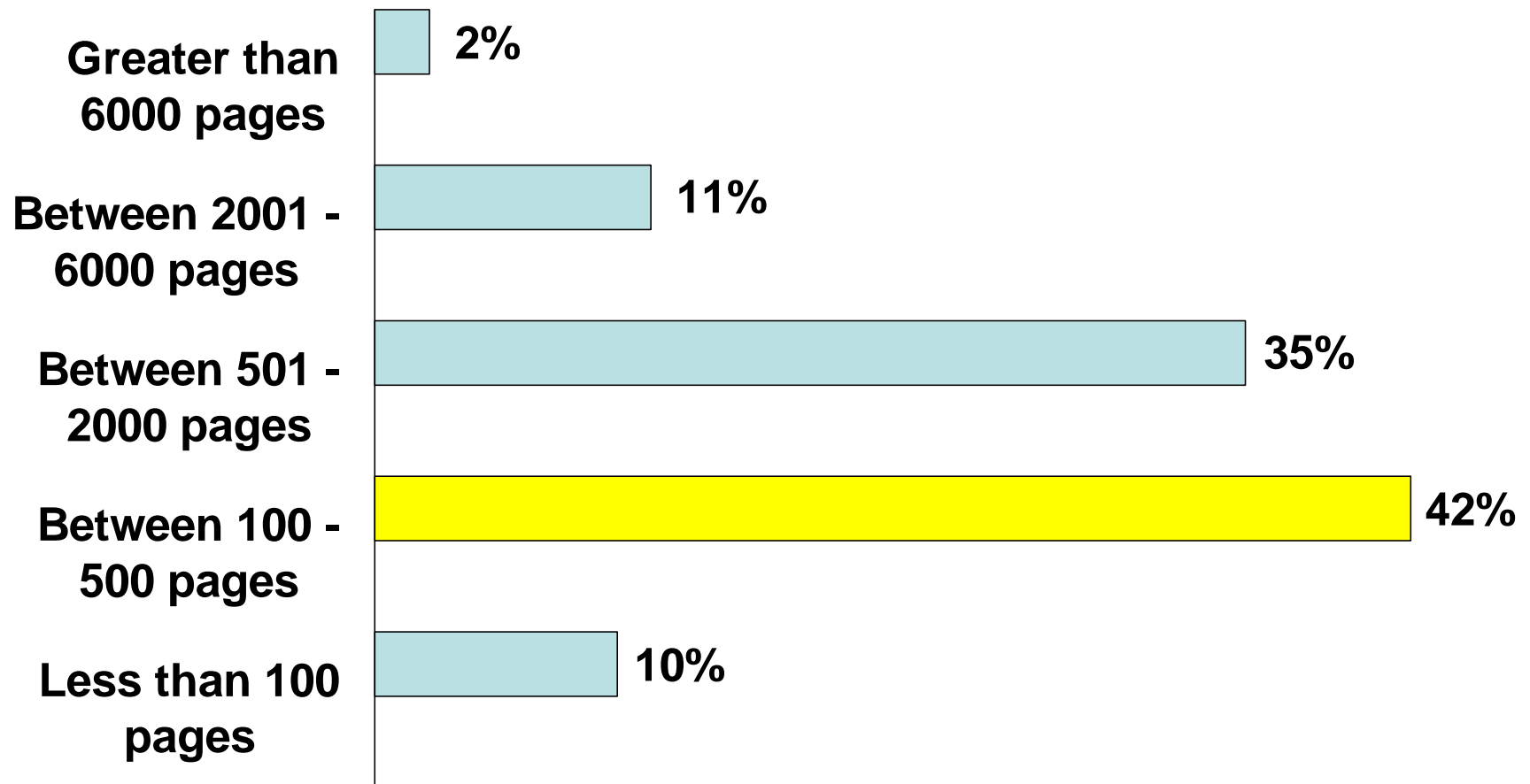
When Firms Addressed the Need for a New 510(k) for New Product Releases



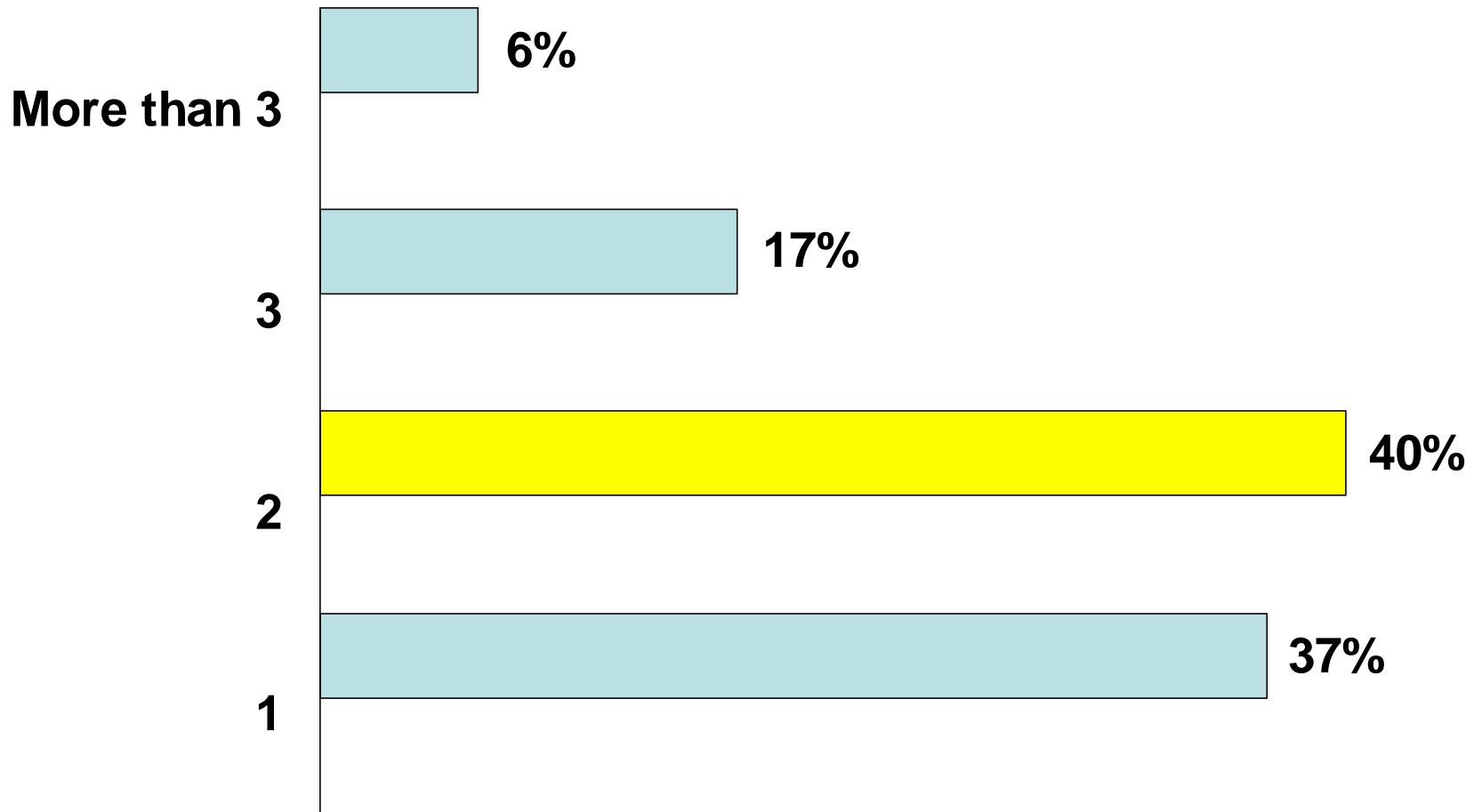
Number of Pages for 510(k) for Least Complex Product Line



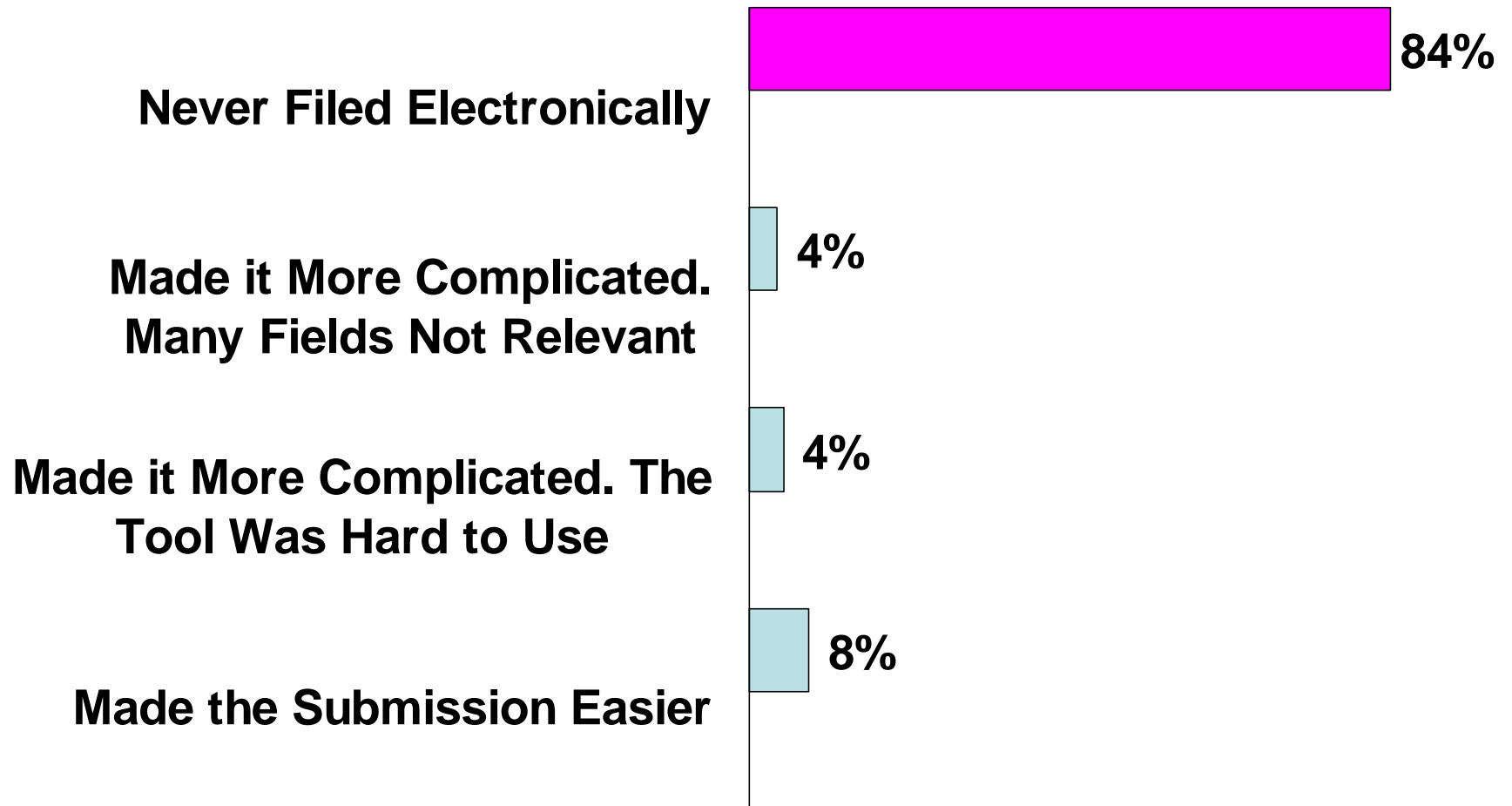
Number of Pages for 510(k) for Most Complex Product Line



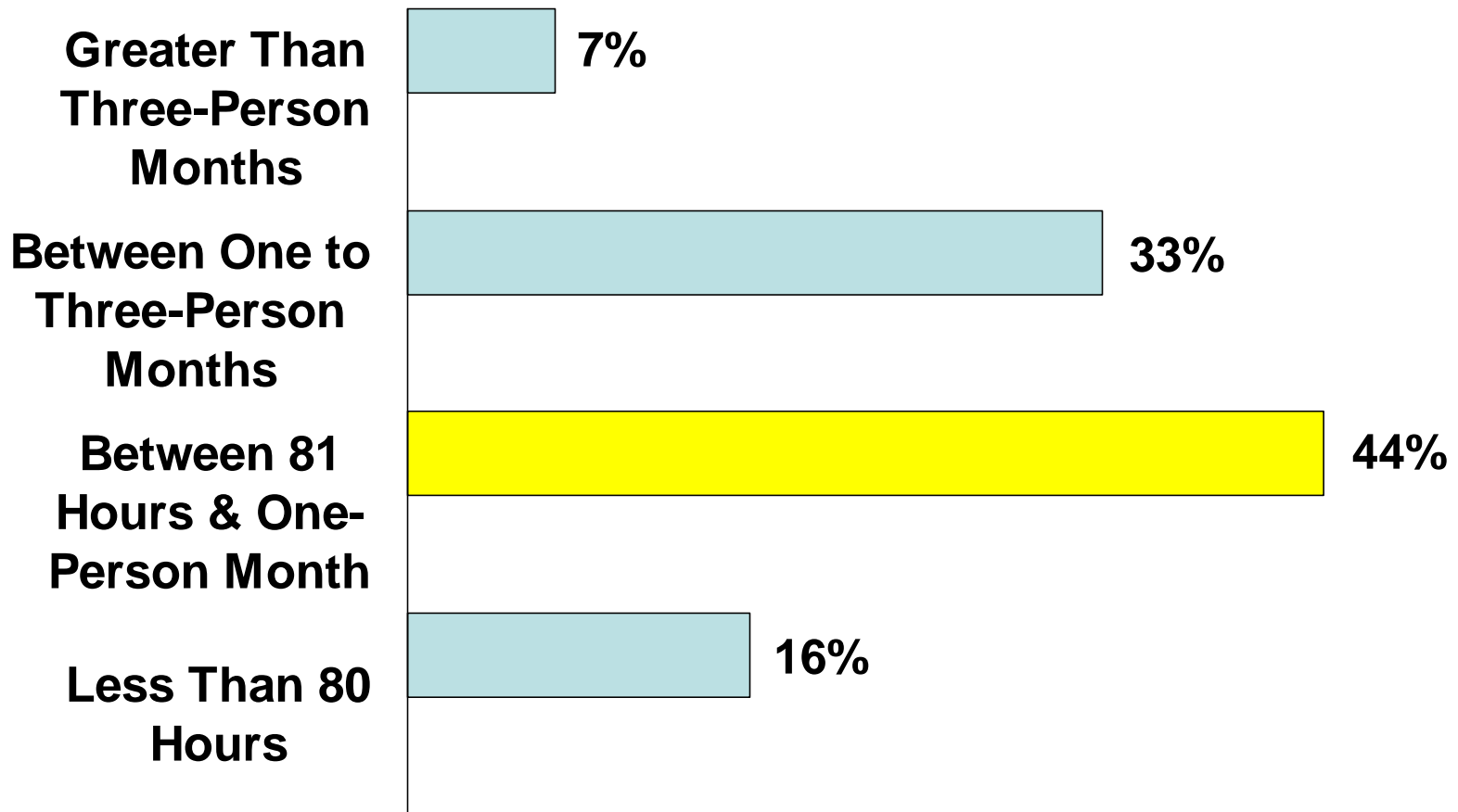
Number of Predicate Devices Used for Comparison in 510(k)



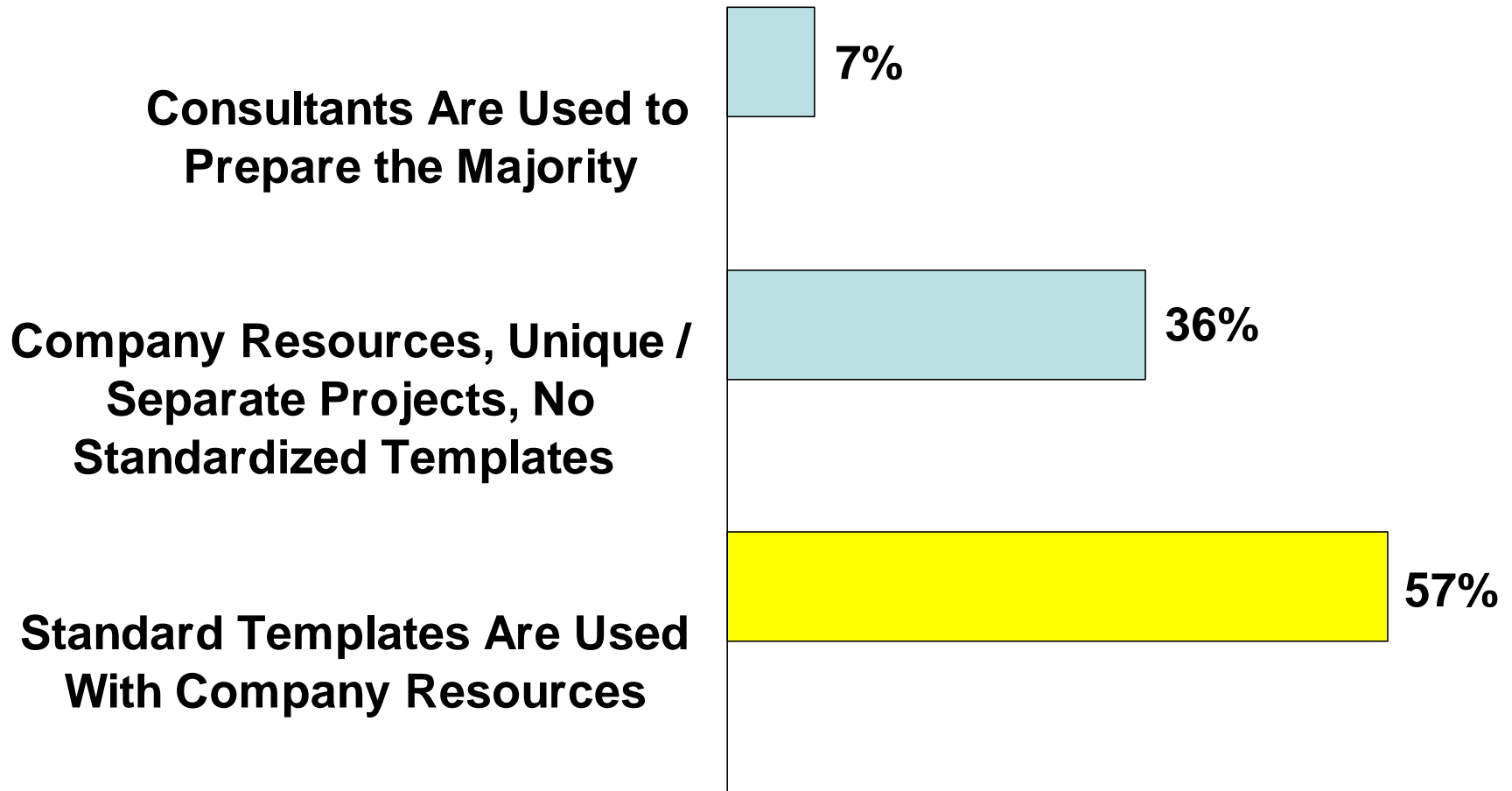
Firms Using FDA's Automated Tools for Electronic Submission of a 510(k)



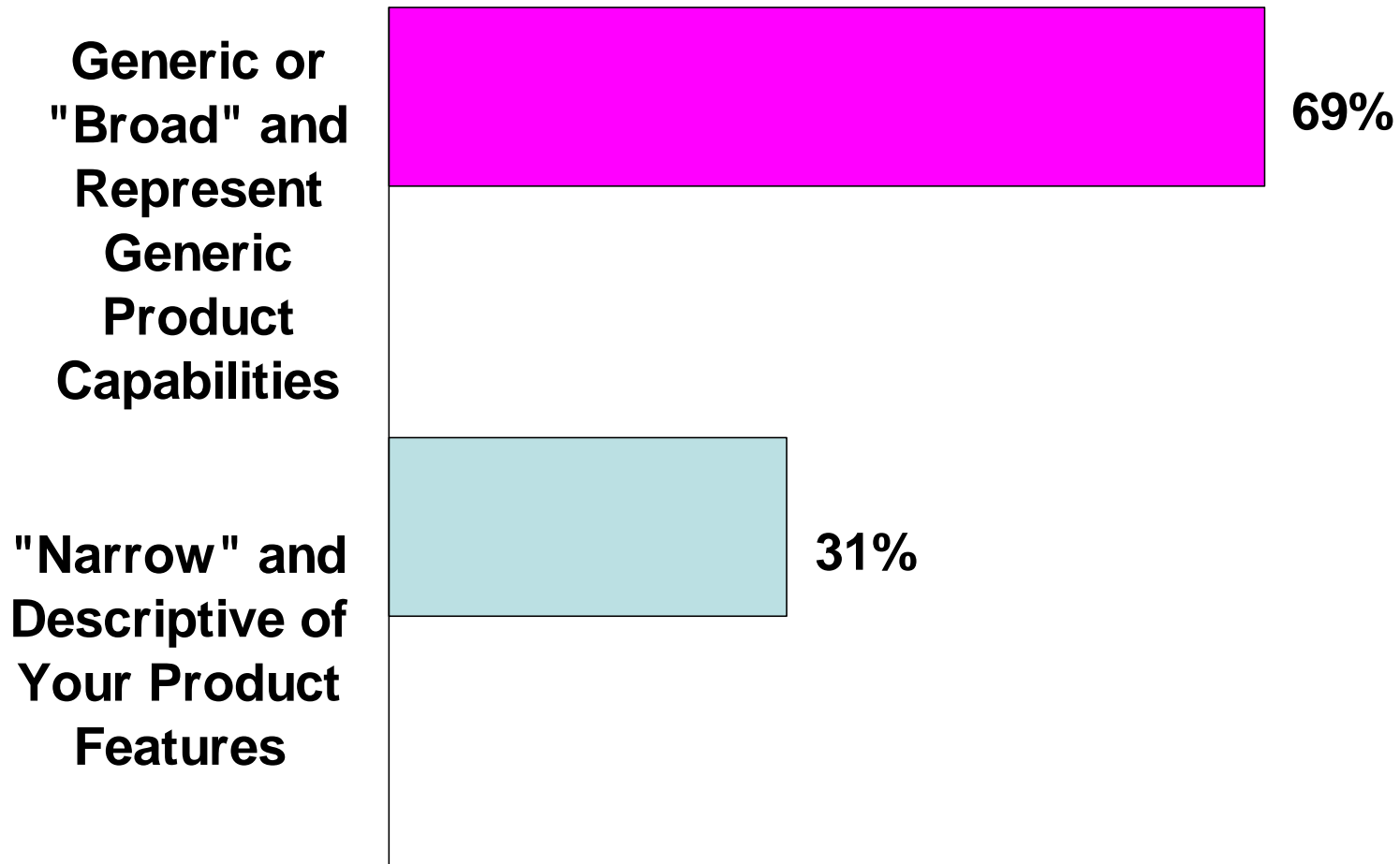
Effort/Time Required to Prepare a 510(k) and Support Responses to Questions



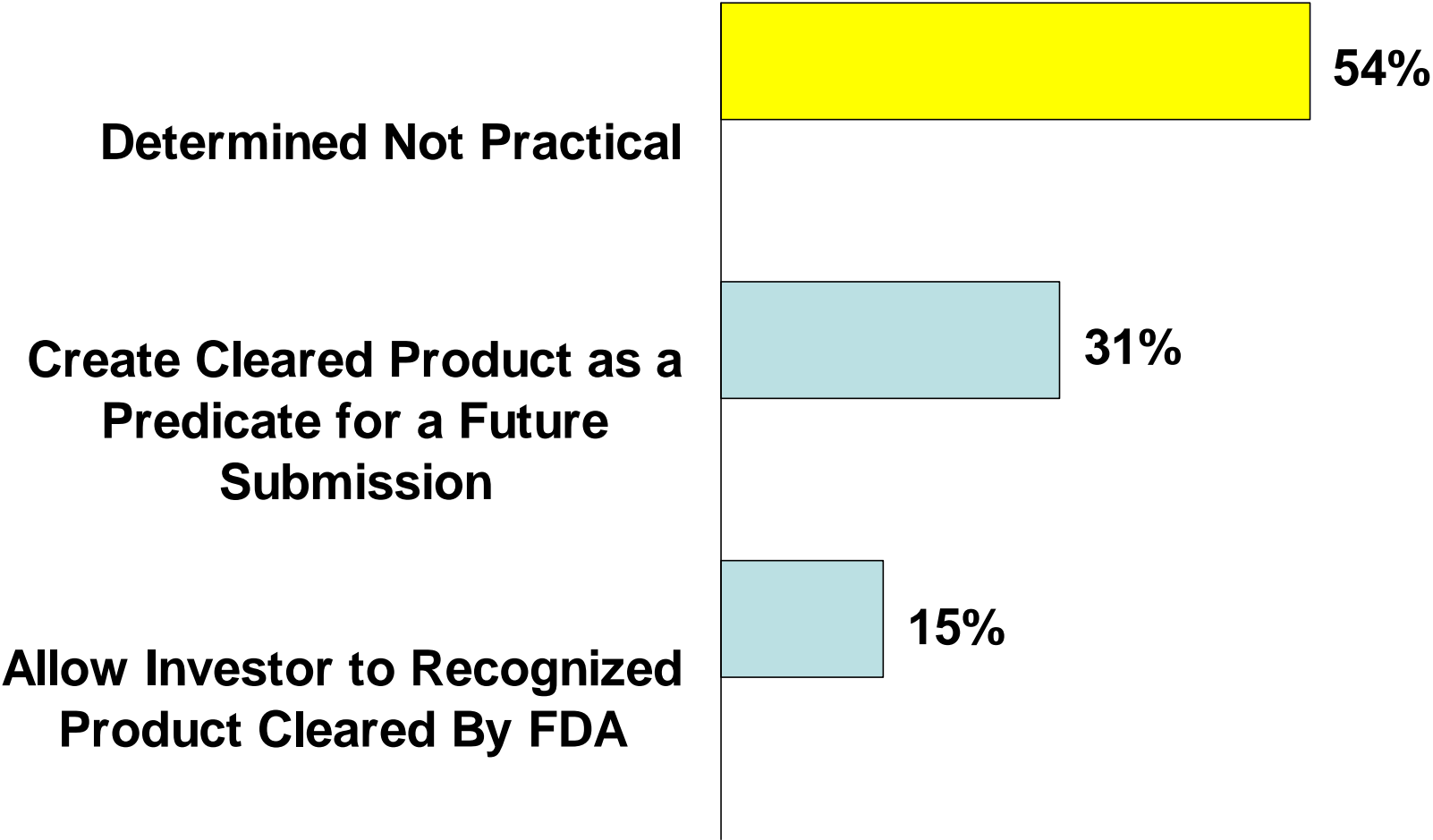
How Firms Prepared their 510(k) Submissions



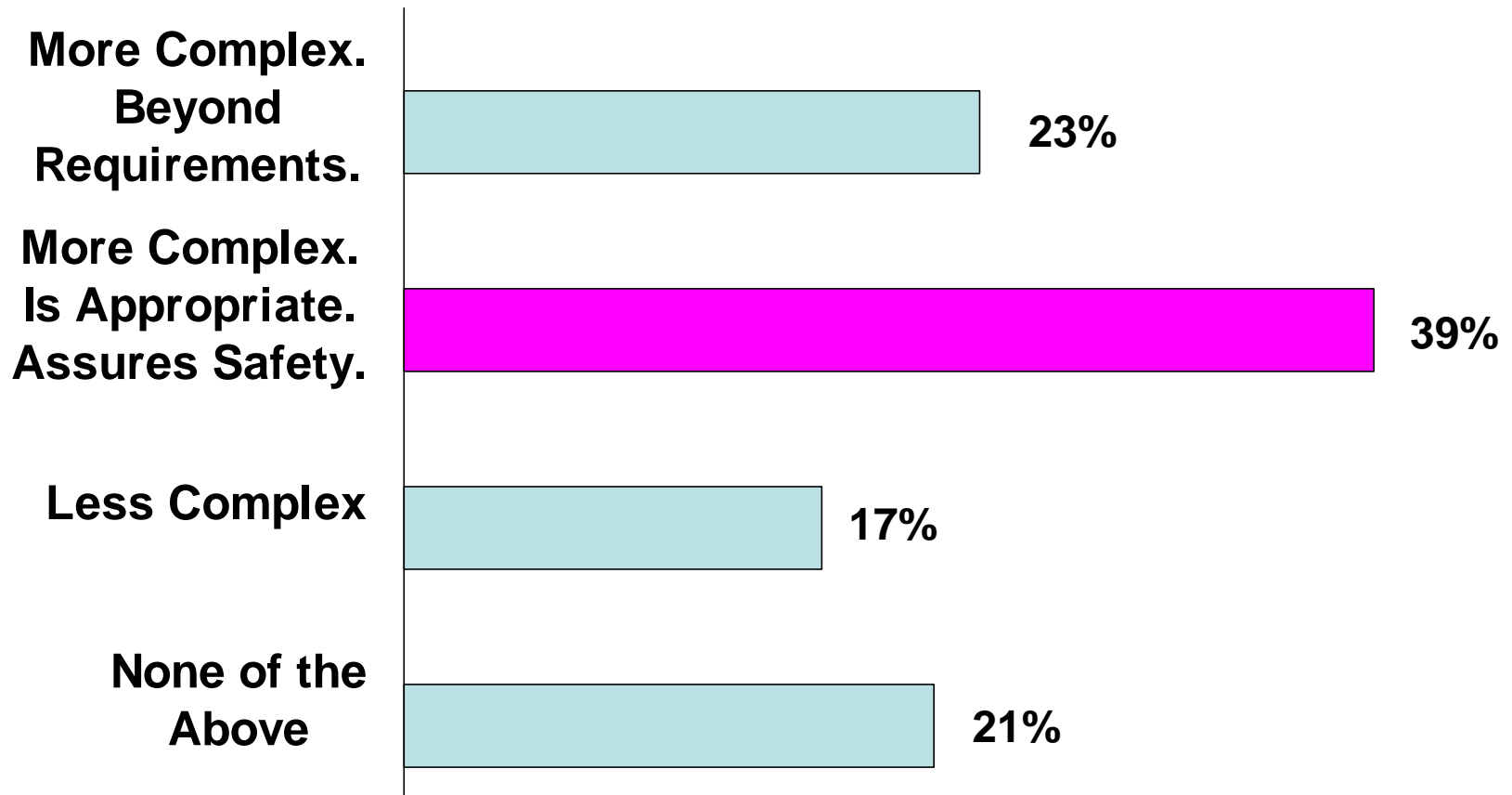
Approach to Defining the 510(k)s' Indication for Use



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



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



Firms Receiving 483 Observation for Failing to Submit a New 510(k) for Changes Made to a Cleared Device



Firms Manufacturing Combination Product

