

Recall Index - Second Quarter 2011

Medical Devices

During the second quarter of 2011, FDA Enforcement Reports documented 233 medical device recalls involving nearly 16 million units. This reflects a 27 percent decrease in recalls over the previous quarter, but a 38 percent increase in the number of recalls over the same quarter last year. The first quarter of 2011 saw 322 recalls involving more than 43 million units. There were ten recalls in the second quarter that involved more than 100,000 units.

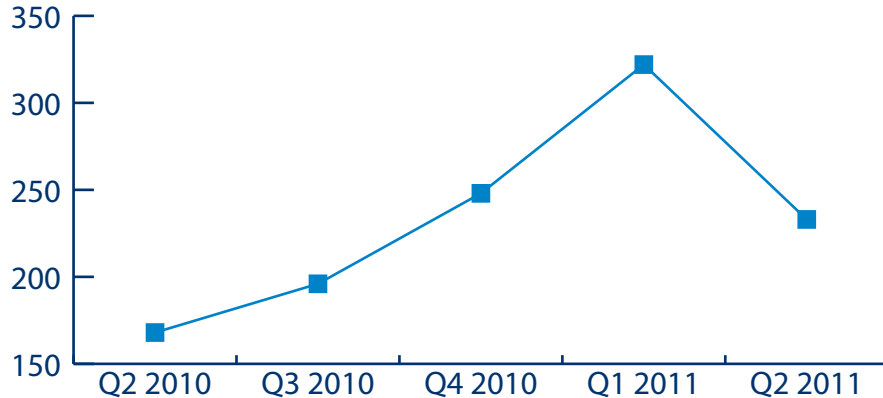
Medical device recalls documented during the second quarter of 2011 affected consumers in the U.S. and overseas. More than 80 percent of recalls affected consumers in the U.S. Nearly 170 recalls affected both domestic and international consumers. Three recalls affected only international consumers during the second quarter.

The ExpertRECALL Index also revealed the following:

- Medical device recalls in the second quarter of 2011 declined for the first time in the past five quarters.
- Second quarter recalls affected the fewest units in the past five quarters.
- More than 30 companies initiated more than one recall in the second quarter.
- Only four percent of recalls in the second quarter of 2011 were classified as Class I.
- Ninety percent of medical device recalls in the second quarter were classified as Class II recalls, accounting for almost 98 percent of all units recalled.

Medical Device Recalls

According to FDA Enforcement Reports



Medical Device Recalls by Class

According to FDA Enforcement Reports

