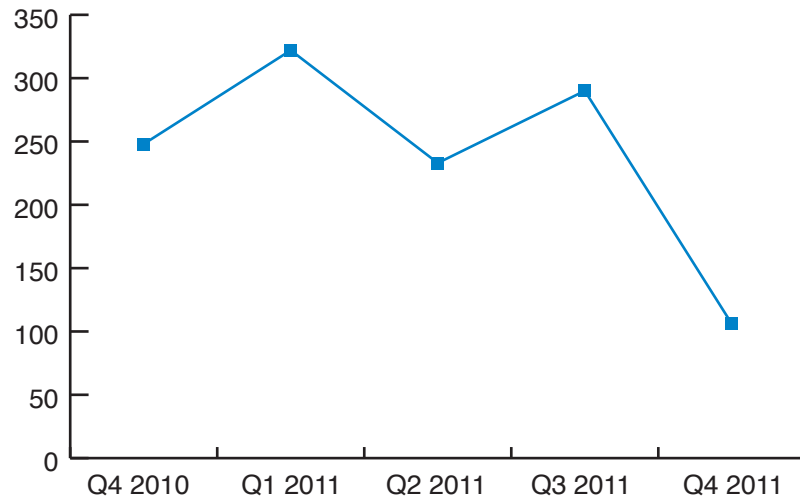


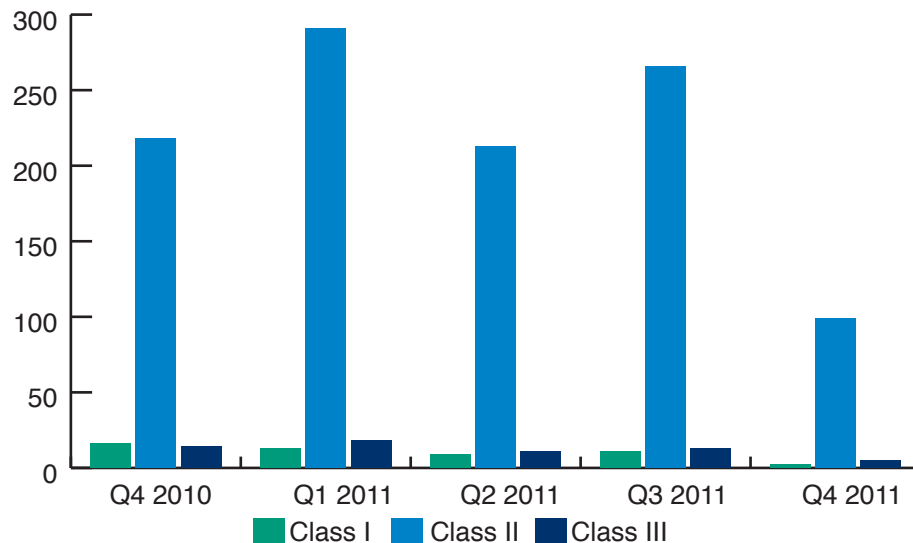
Recall Index - Fourth Quarter 2011

Medical Devices

Medical Device Recalls
According to FDA Enforcement Reports



Medical Device Recalls by Class
According to FDA Enforcement Reports



During the fourth quarter of 2011, FDA Enforcement Reports documented 106 medical device recalls involving more than 13 million units. This reflects a more than 63 percent decrease in recalls over the previous quarter, and a more than 57 percent decrease in the number of recalls over the same quarter last year.

Medical device recalls in the fourth quarter affected consumers both in the U.S. and overseas. Of the 106 recalls documented in FDA enforcement reports, 98 affected customers nationwide. Seventy-three recalls affected customers in both the U.S. and at least one other territory or country. Three recalls affected only customers outside the U.S.

The ExpertRECALL Index also revealed the following:

- Medical device recalls decreased in the fourth quarter of 2011; fourth-quarter recalls reached the lowest number of recalls documented in the last five quarters.
- Fourth-quarter recalls affected less than half the number of units as recalls documented in the third quarter of 2011.
- Four recalls in the fourth quarter affected more than 1 million units.
- Less than 2 percent of recalls in the fourth quarter of 2011 were classified as Class I; these recalls affected less than 1 percent of all units recalled in the quarter.
- More than 93 percent of medical device recalls in the fourth quarter were classified as Class II recalls, accounting for more than 99 percent of all units recalled.
- More than 60 companies initiated at least one recall in the fourth quarter; more than a dozen companies issued more than one recall.