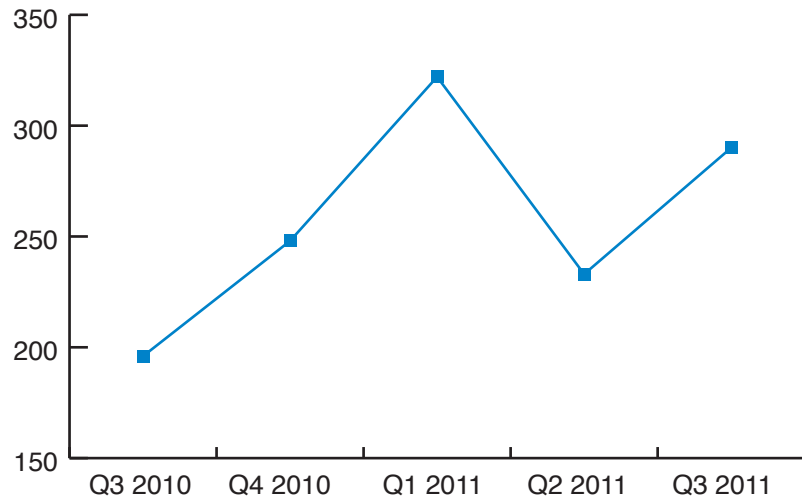


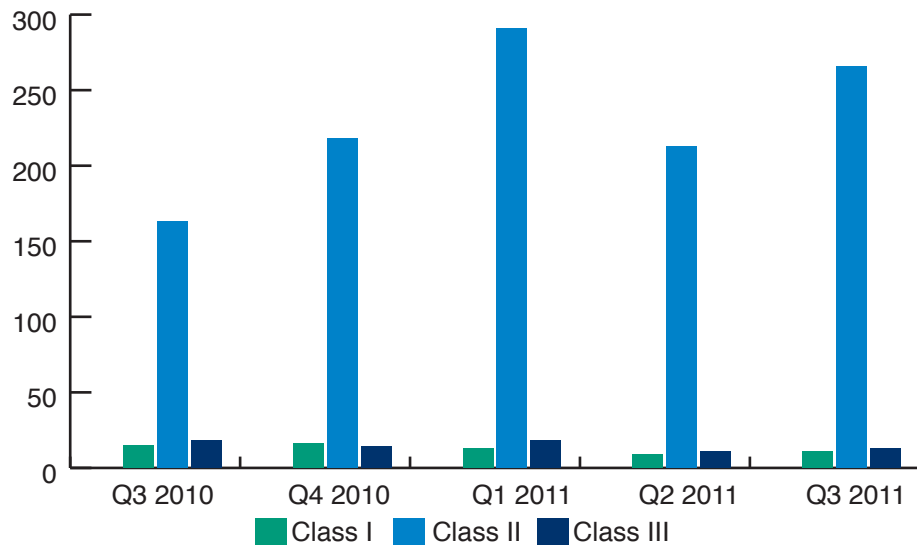
# Recall Index - Third Quarter 2011

## Medical Devices

Medical Device Recalls  
According to FDA Enforcement Reports



Medical Device Recalls by Class  
According to FDA Enforcement Reports



During the third quarter of 2011, FDA Enforcement Reports documented 290 medical device recalls involving nearly 30 million units. Medical device recalls increased less than 5 percent in the third quarter when compared to the average number of events of the previous two quarters. The second quarter of 2011 saw 233 recalls involving nearly 16 million units, and the first quarter of 2011 saw 322 recalls involving more than 43 million units.

Medical device recalls documented during the third quarter of 2011 affected consumers in the U.S. and overseas. About 95 percent of recalls affected customers nationwide, while 3 recalls affected only customers outside the U.S. There were 201 recalls that affected both domestic and international customers.

The ExpertRECALL Index also revealed the following:

- Third quarter recalls affected nearly twice the number of units as the second quarter of 2011.
- More than 130 companies initiated at least one recall in the third quarter; more than 40 companies issued more than one recall.
- Less than four percent of recalls in the third quarter of 2011 were classified as Class I; these recalls affected less than 2 percent of all units recalled in the quarter.
- More than 90 percent of medical device recalls in the third quarter were classified as Class II recalls, accounting for almost 98 percent of all units recalled.