FDA Approvals of Innovative Devices Fell Off a Cliff in 2013

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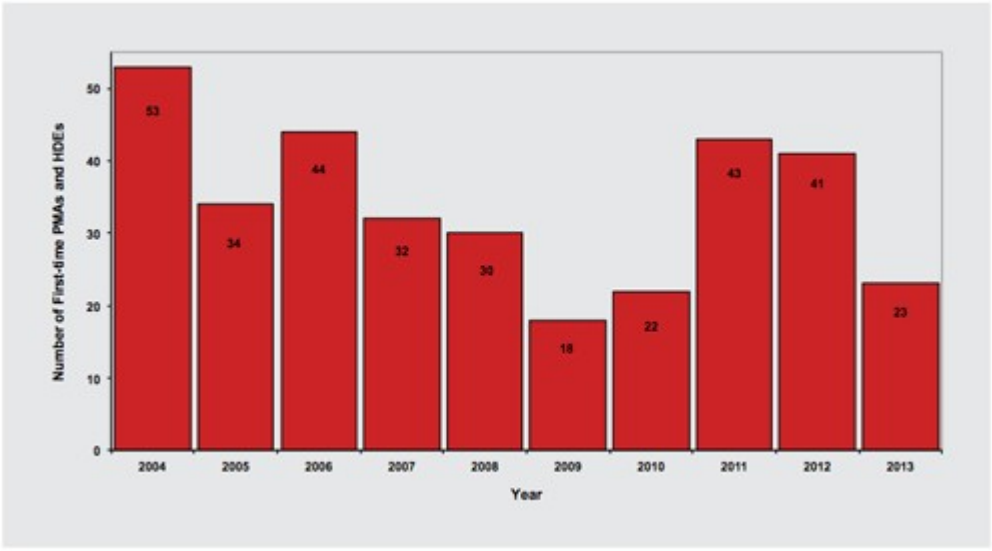
A overview of medtech in 2013 shows how the number of FDA approvals of first-time PMA and humantarian-exemption devices was nearly halved from the year before.

A new report on medtech shows that premarket approvals for innovative devices fell to just 23 last year, down 44% from 41 approvals in 2012.

The number of first-time PMAs and humanitarian device exemptions (HDEs) granted last year is a tad better than the lowest number of approvals - 18 in 2010 - granted in a decade, according to EP Vantage publishing arm of the life science business intelligence company Evaluate Group.

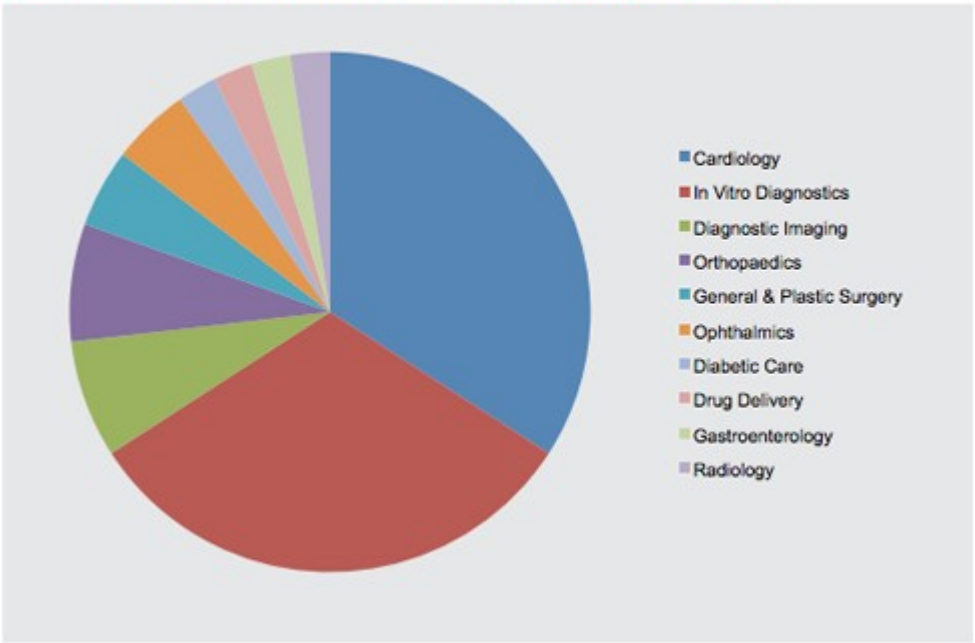
FDA Approval Activity

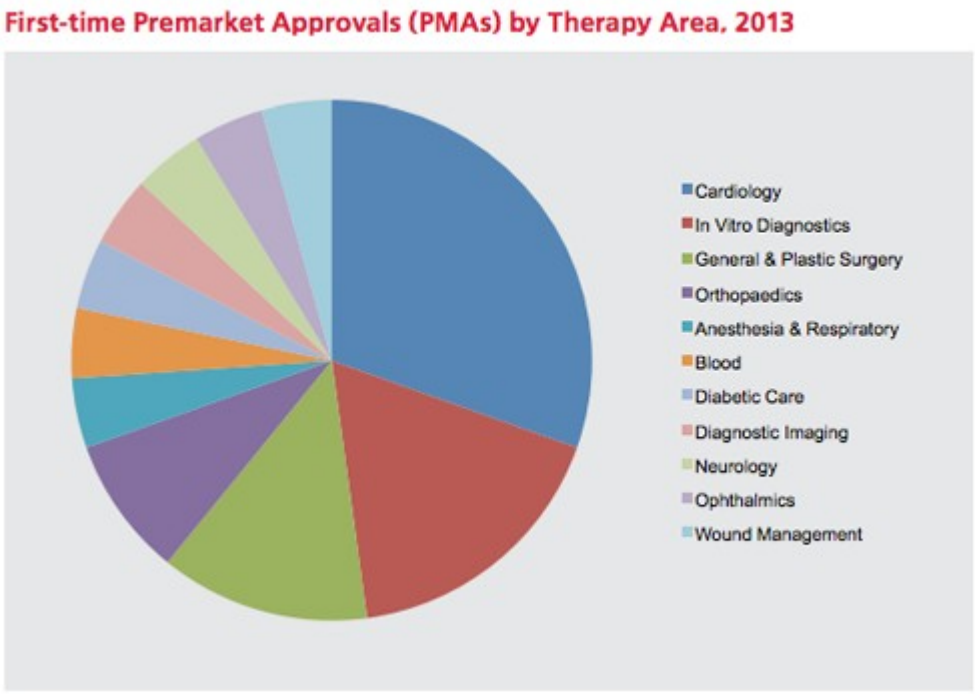


It is also interesting to note how the category in which PMAs and HDEs were granted shifted between 2012 and 2013. In 2012, there were no wound management PMA devices that got the green signal from the FDA. That changed in 2013 when ArterX, a surgical sealant, from Tenaxis Medical won approval.

The same goes for the anesthesia and respiratory category of therapy that contained no PMAs in 2012. But in 2013, Johnson and Johnson won approval for its Sedasys computer-assisted sedation system. However, the world's first computer-assisted sedation system was initially rejected by the FDA in 2010.

First-time Premarket Approvals (PMAs) by Therapy Area, 2012





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