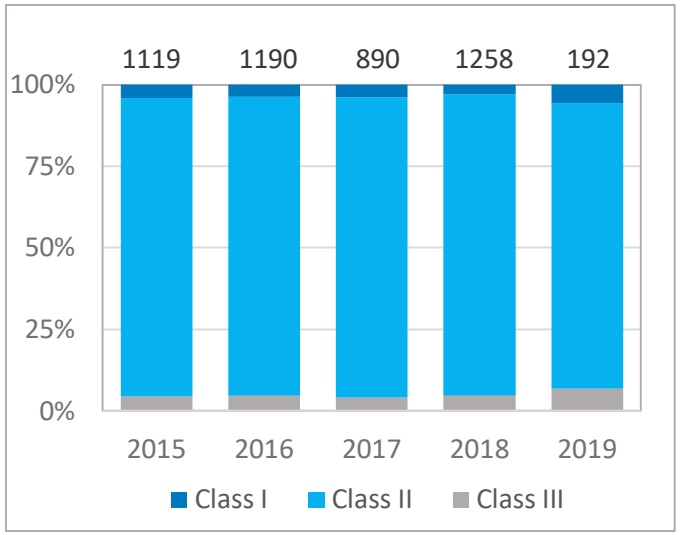
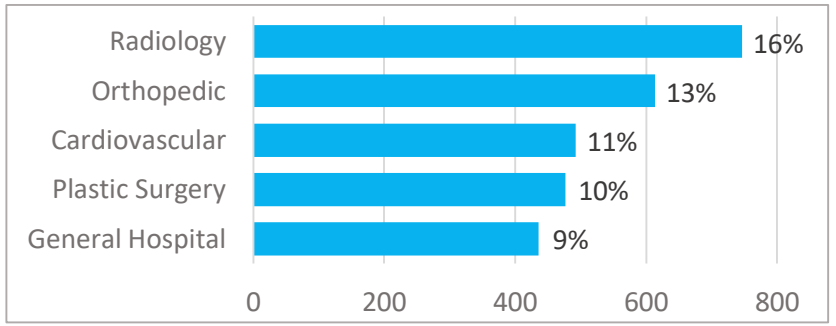
Medical Device Recalls (2015-Apr 2019)

Total Events by Recall Classification [1]

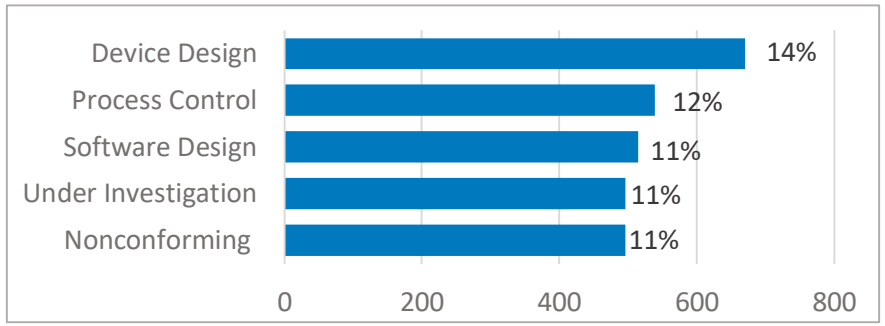


Class I	Situation in which there is a reasonable probability that the use of, or exposure to, a violative product **will cause serious adverse health consequences or death**.
Class II	Situation in which use of, or exposure to, a violative product may cause temporary or **medically reversible adverse health consequences** or where the probability of serious adverse health consequences is remote.
Class III	situation in which use of, or exposure to, a violative product is **not likely to cause adverse health consequences**.

Top 5 Medical Specialties (~ 60% of total events)[2]

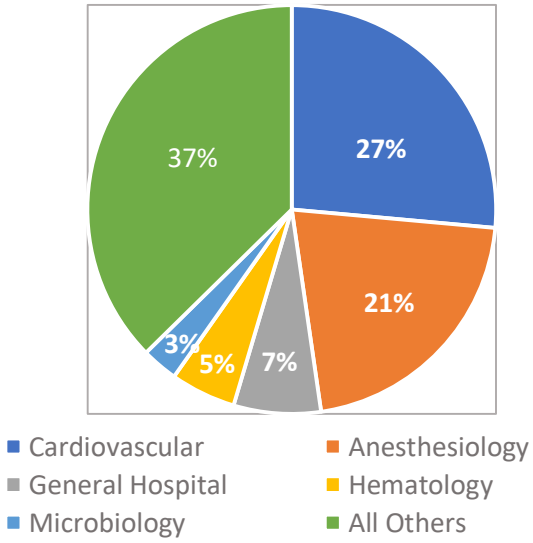


Top 5 Reasons for Recalls[2]



Class I Recall Events Deep Dive

Total Class I Events = 174



Top Devices and Reasons for Class I Recall Events

Device Code	Device Name	Device Class	Top Reason for Recall
CBK	Ventilator, continuous, facility use	2	Device Design
DSQ	Ventricular (assist) bypass	3	Device Design
MKJ	Automated external defibrillator	3	Device Design
DQY	Catheter, percutaneous	2	Process Control
BSZ	Gas machine, anesthesia	2	Nonconforming
DSP	System, balloon, intra-aortic control	2	Device Design
DYB	Introducer, catheter	2	Nonconforming
DQO	Catheter, intravascular, diagnostic	2	Component Design

Notes:

1. Numbers above the bars represent distinct count of recall events for each year. 2019 data through April only.
2. Percent values based on total recall events (2015 – Apr 2019 total = 4649; Filtered for Device classes 1, 2, 3 only).

About Exeed™

Portfolio of Innovative Quality Solutions in 4 Broad Areas

Customer Experience

Regulatory Compliance

Risk Management

Quality Culture

Email: Info@ExeedQM.com
Web: www.ExeedQM.com
Phone: 1-833-MY-EXEED