Medical Device Recall Report FY 2003- FY 2012

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Questions

- **Why did FDA draft the Medical Device Recall Report?**
- **Why has the number of recalls increased since 2003?**
- **What types of devices are frequently recalled? And why?**
- **What is happening with Class I recalls?**
- **Can FDA reduce internal processing times?**

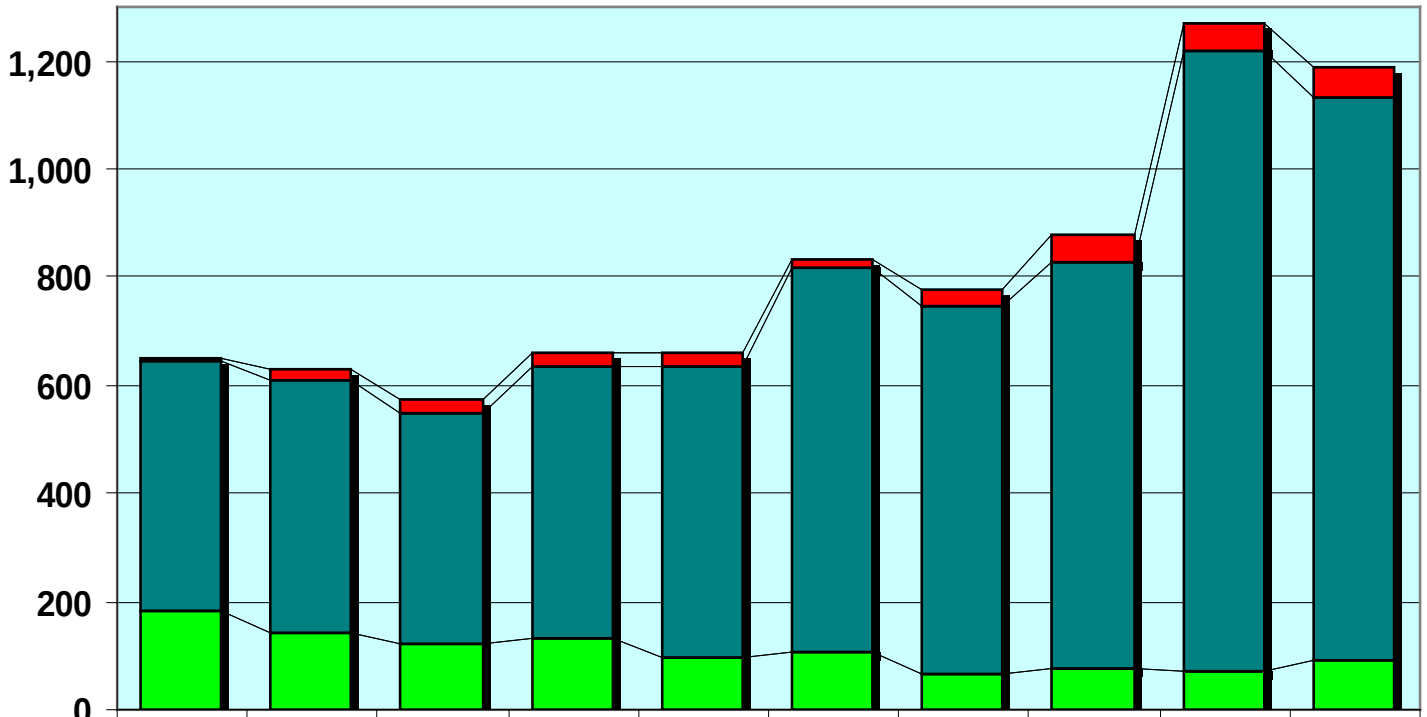
WHY the report?

FDA Case for Quality (August 2011)

GAO report Medical Device Recalls (June 2011)

FDASIA Section 605 (July 2012)

Medical Device Recalls



	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Class I	7	24	26	22	26	14	32	49	50	57
Class II	460	466	422	505	540	710	677	753	1152	1043
Class III	183	141	124	132	96	108	67	74	69	90
Totals	*650*	*631*	*572*	*659*	*662*	*832*	*776*	*876*	*1,271*	*1,190*

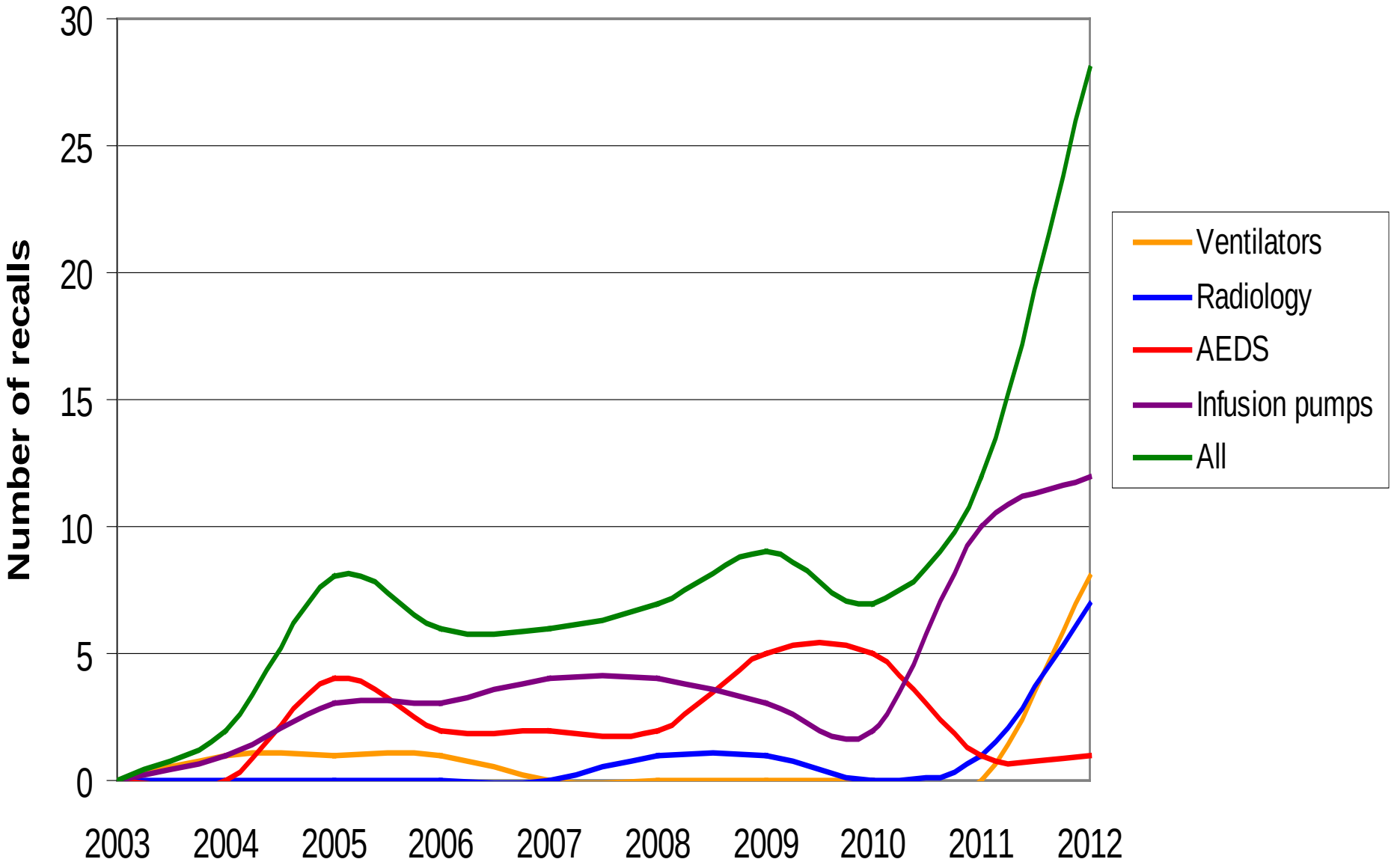
Reason #1 for Recall Increases Industry Growth

	Registered Establishments	Medical Device Listings
FY2008	19,153	117,618
FY2009	20,270	116,706
FY2010	21,552	129,875
FY2011	23,943	150,307
FY2012	24,133	157,441

Reason #2 for Recall Increases Device Specific Initiatives

Addressed high risk and problematic device types – across manufacturers

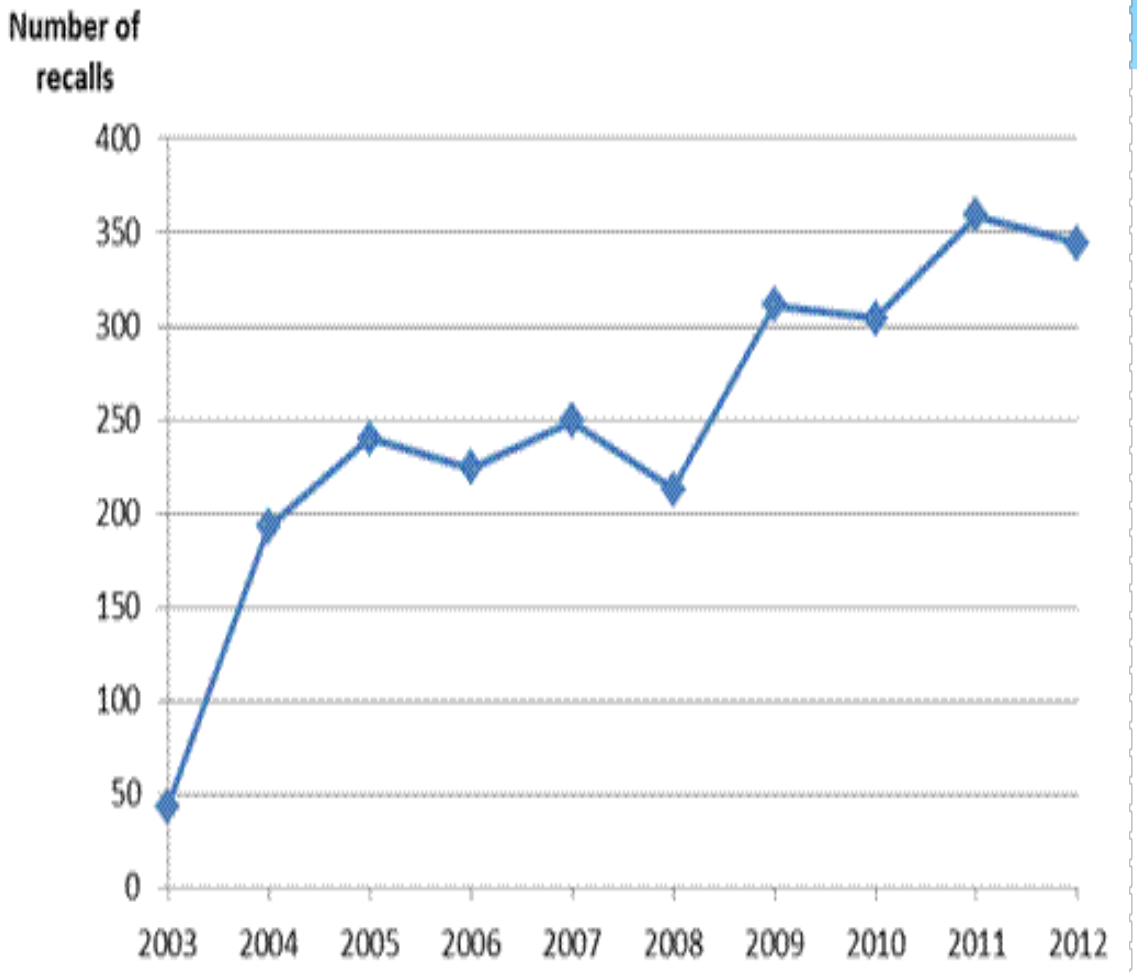
- **AEDs**
- **Ventilators**
- **Infusion Pumps**
- **Radiation Safety**


Number of recalls
30
25
20
15
10
5
0
2003
2004
2005
2006
2007
2008
2009
2010
2011
2012
Ventilators
Radiology
AEDS
Infusion pumps
All

Reason #3 - FDA Inspections

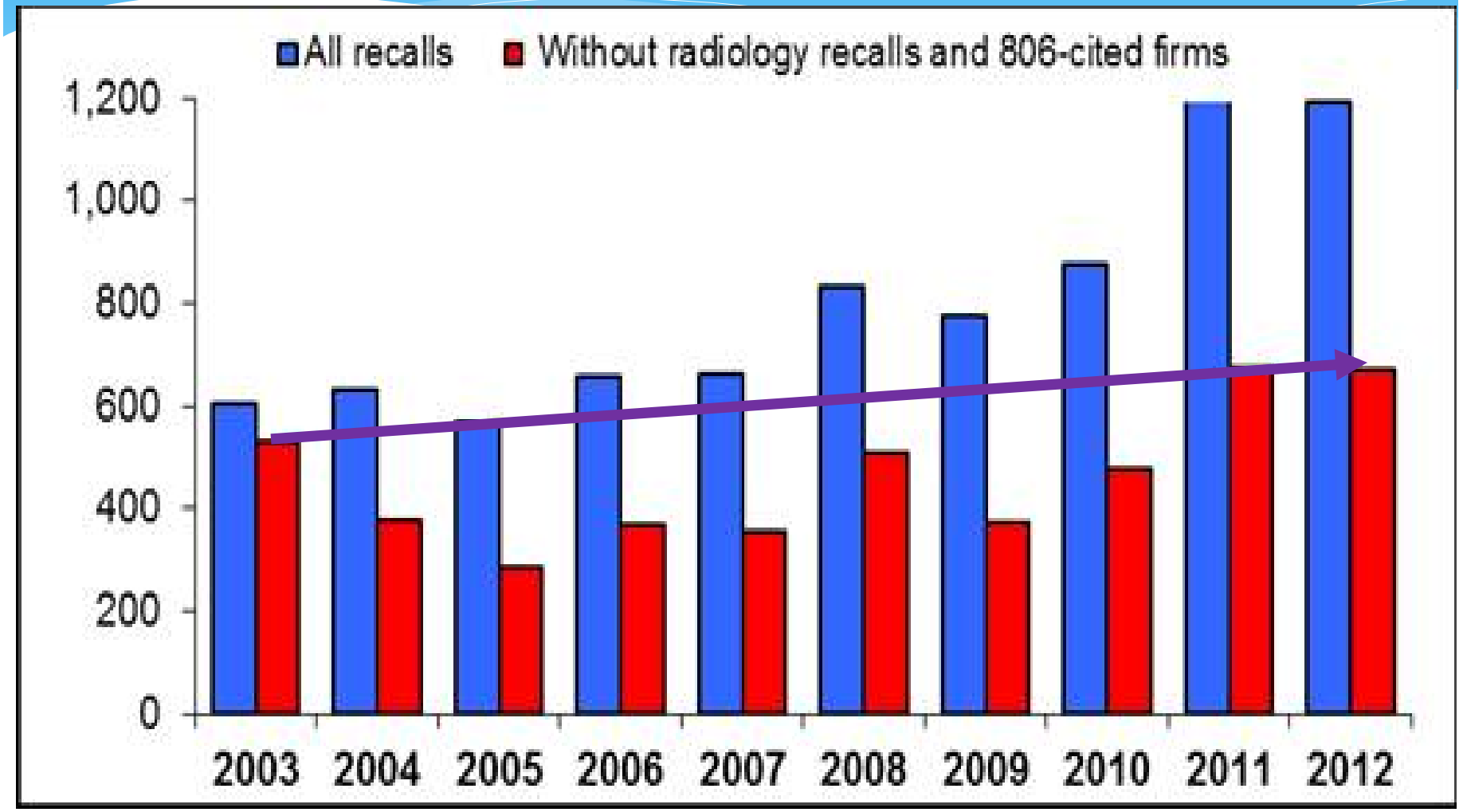
- **Recalls are reported voluntarily by manufacturers**
- **About 3,000 device firms are inspected each year**
- **How do inspections effect recalls?**

Number of Recalls Reported by Firms with 21 CFR 806 Observations

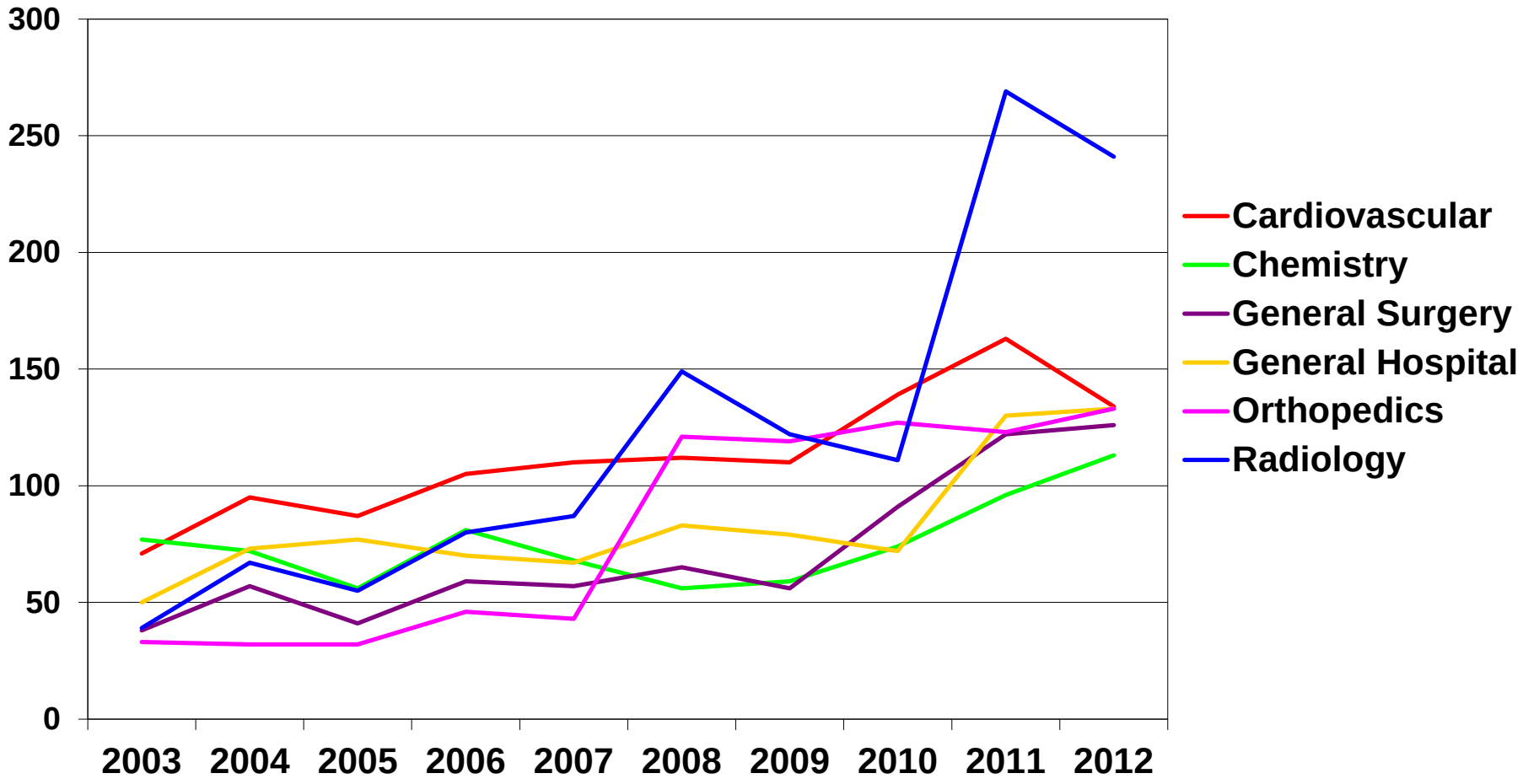


- ~46 firms receive an 806 citation on a 483 each year
- Chart shows recalls for these 364 firms
- After getting "dinged", recall reporting improves

Adjusted Recall Counts FY 2003 - FY 2012



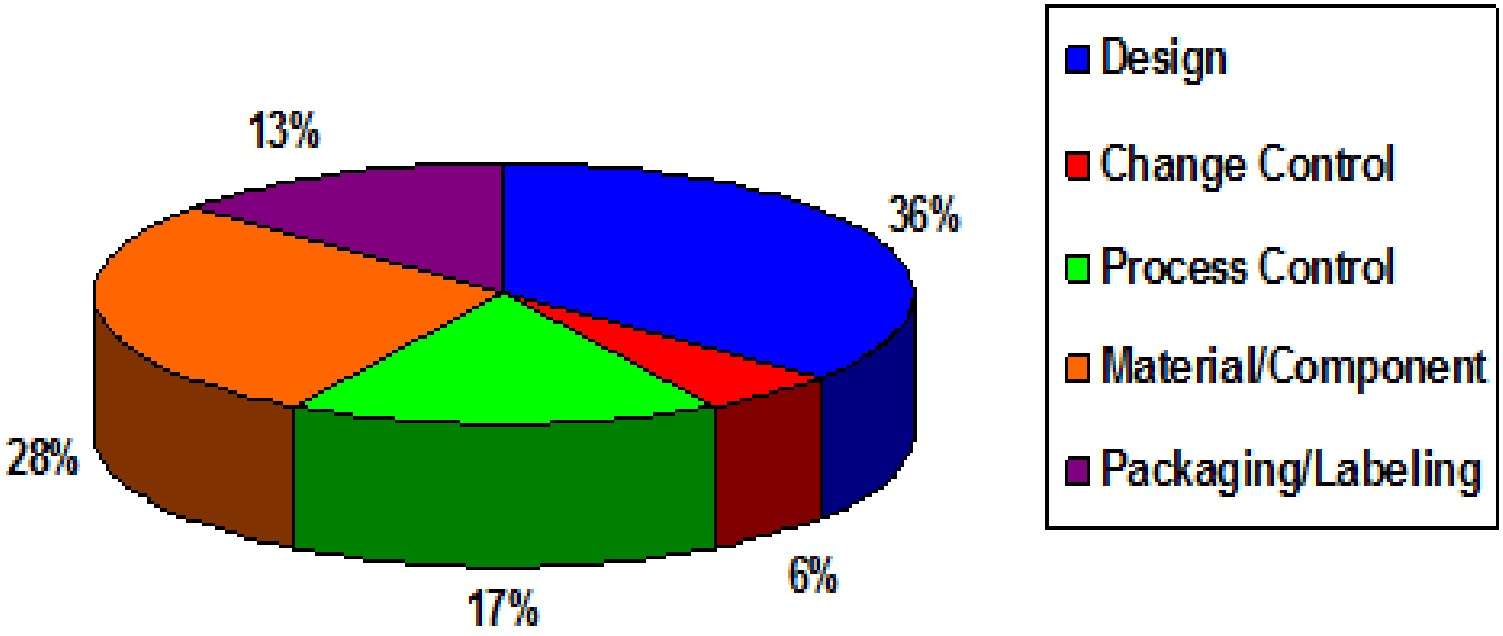
WHAT kind of devices?



Top 10 Procodes in 10 years

Recalls	Procode	Product description	Specialty
176	IYE	ACCELERATOR, LINEAR, MEDICAL	Radiology
153	LLZ	SYSTEM, IMAGE PROCESSING, RADIOLOGICAL	Radiology
130	FRN	PUMP, INFUSION	Gen Hospital
115	JAK	SYSTEM, X-RAY, TOMOGRAPHY, COMPUTED	Radiology
109	MKJ	AUTOMATED EXTERNAL DEFIBRILLATORS	Cardiovascular
106	GEI	ELECTROSURGICAL, CUTTING & COAGULATION & ACCESSORIES	Surgery
101	JJE	ANALYZER, CHEMISTRY, FOR CLINICAL USE	Chemistry
98	JQP	CALCULATOR/DATA PROCESSING MODULE, FOR CLINICAL USE	Chemistry
97	GKZ	COUNTER, DIFFERENTIAL CELL	Hematology
96	JWH	PROSTHESIS, KNEE, PATELLOFEMOROTIBIAL, SEMI-CONSTRAINED	Orthopedic

Recall Reasons



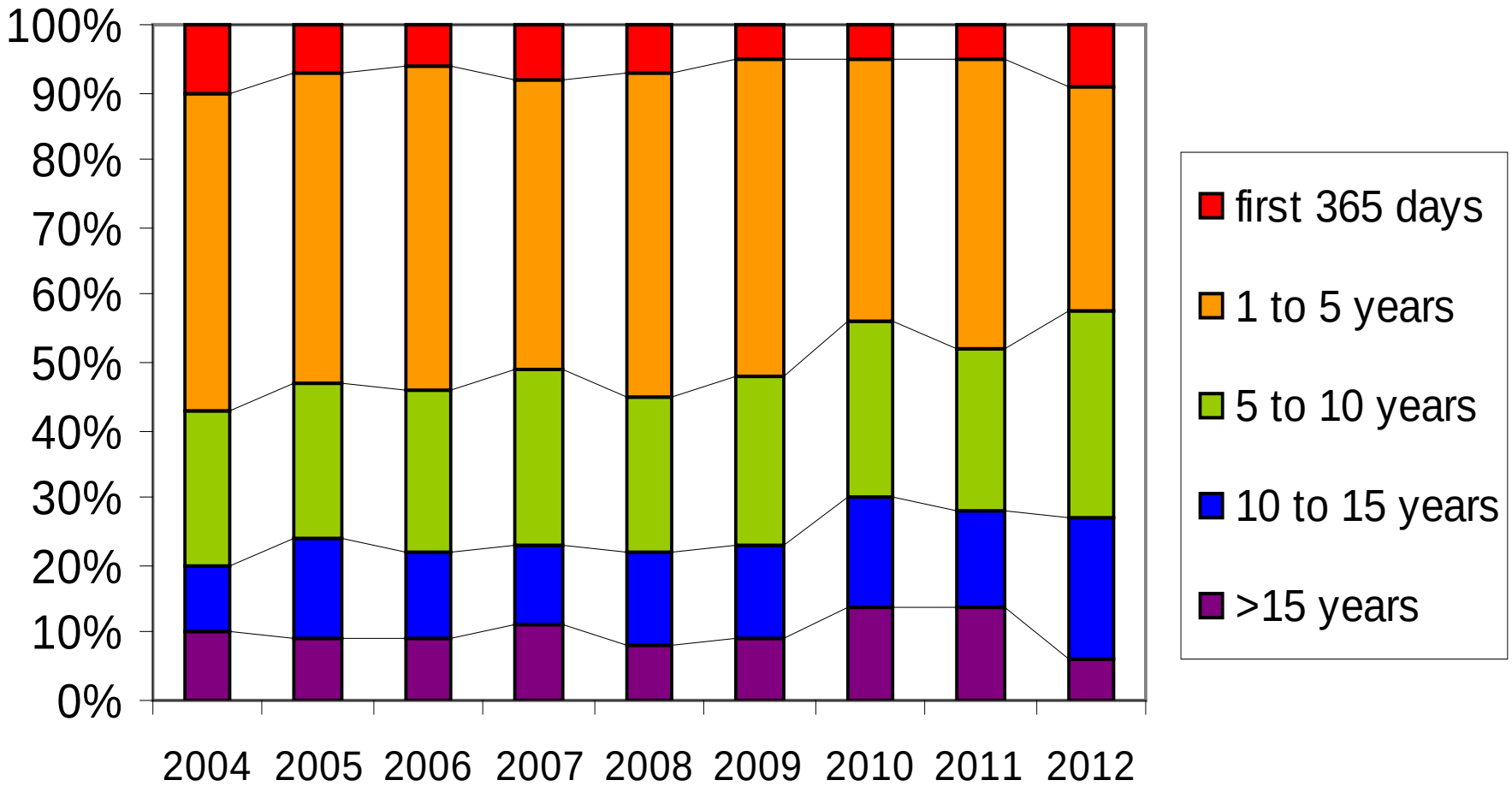
Top Recall Regulatory Violations

Number	Regulation Subpart Title	Class I	Class II	Class III
820.30	Design controls and related subparts	703	1,759	36
820.80	Receiving, in-process, and finished device acceptance	204	1,068	61
820.70	Production and process controls and subparts	119	830	58
820.90	Nonconforming product	17	415	28
820.75	Process Validation	16	390	30
820.50	Purchasing controls	19	366	29
820.130	Device packaging	0	377	5
820.120	Device labeling and related subparts	2	271	29
820.25	Personnel	0	159	2
820.100	Corrective and preventive action	0	122	7

Software- related

	Software Change Control	Software Design	Software Design (manufacturing process)	Sum	% of all CDRH Recalls
2008	13	141	2	156	18.3%
2009	9	111	1	121	15.4%
2010	4	73	3	80	8.9%
2011	11	182	10	203	15.8%
2012	12	169	5	186	15.5%
Sum/Overall:	49	676	21	746	15.1%

Recalled device time on market

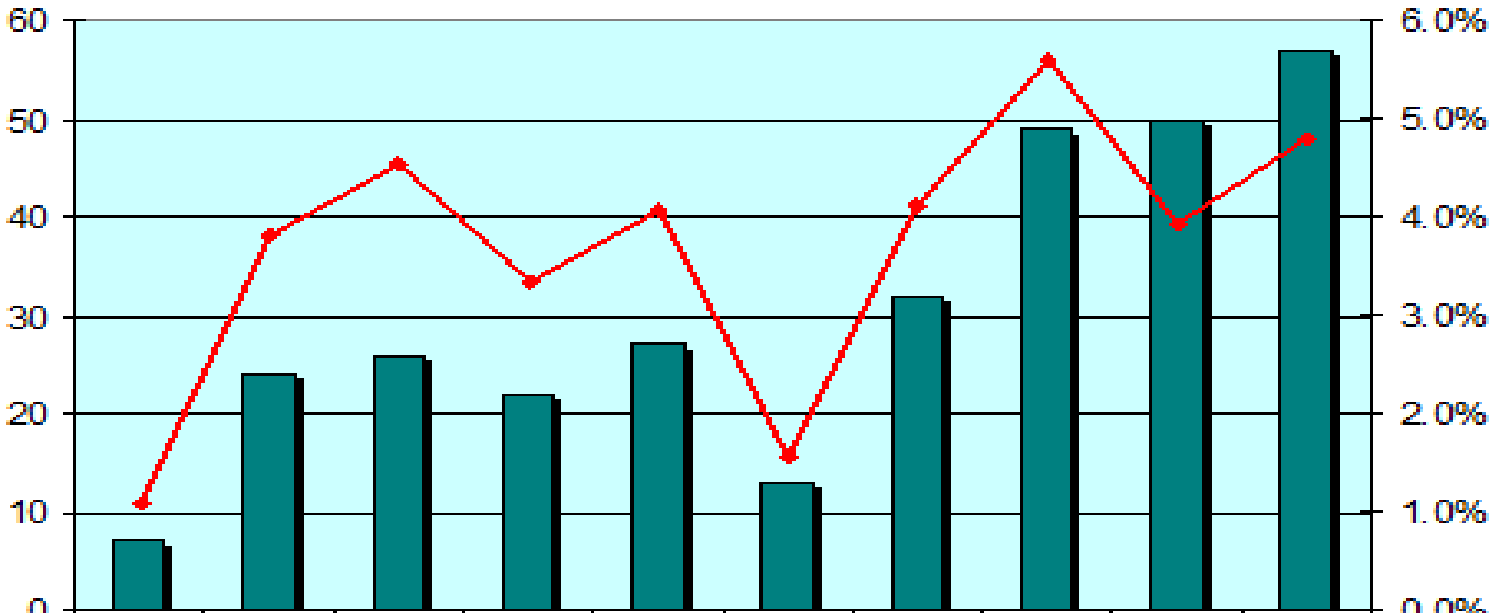


Foreign vs Domestic Reporting

Figure 19: Proportion of Foreign and Domestic Manufacturer Registration and Recall	US % of Mfg Registration	Foreign % of Mfg Registration	US Mfg % of Recalls	Foreign Mfg % of Recalls
FY 2010	48.4%	51.6%	81.8%	18.2%
FY 2011	47.6%	52.4%	82.7%	17.3%
FY 2012	46.7%	53.3%	79.5%	20.5%

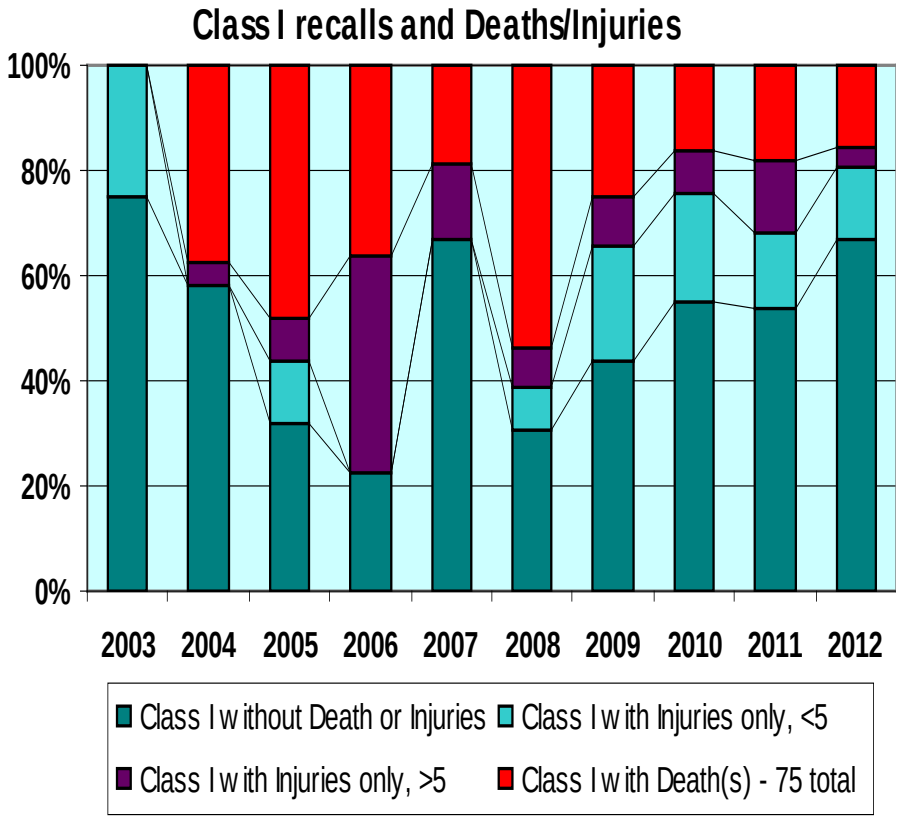
What about Class I recalls?

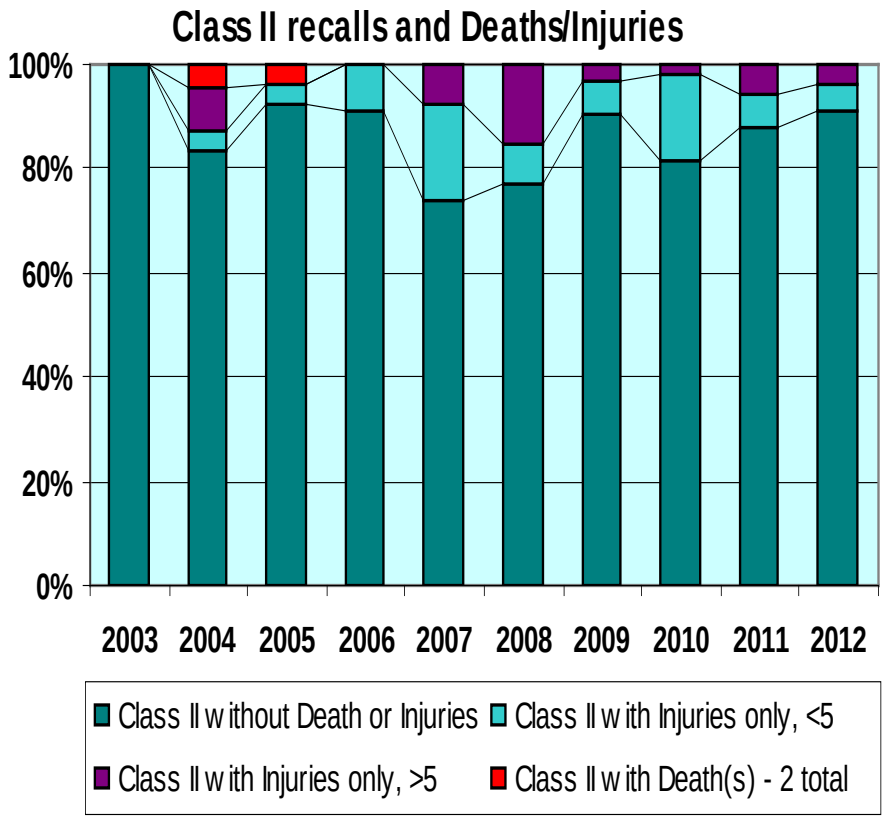
- **Has FDA changed processes?**
- **Have manufacturers changed processes?**
- **Do devices pose more risk to the public?**



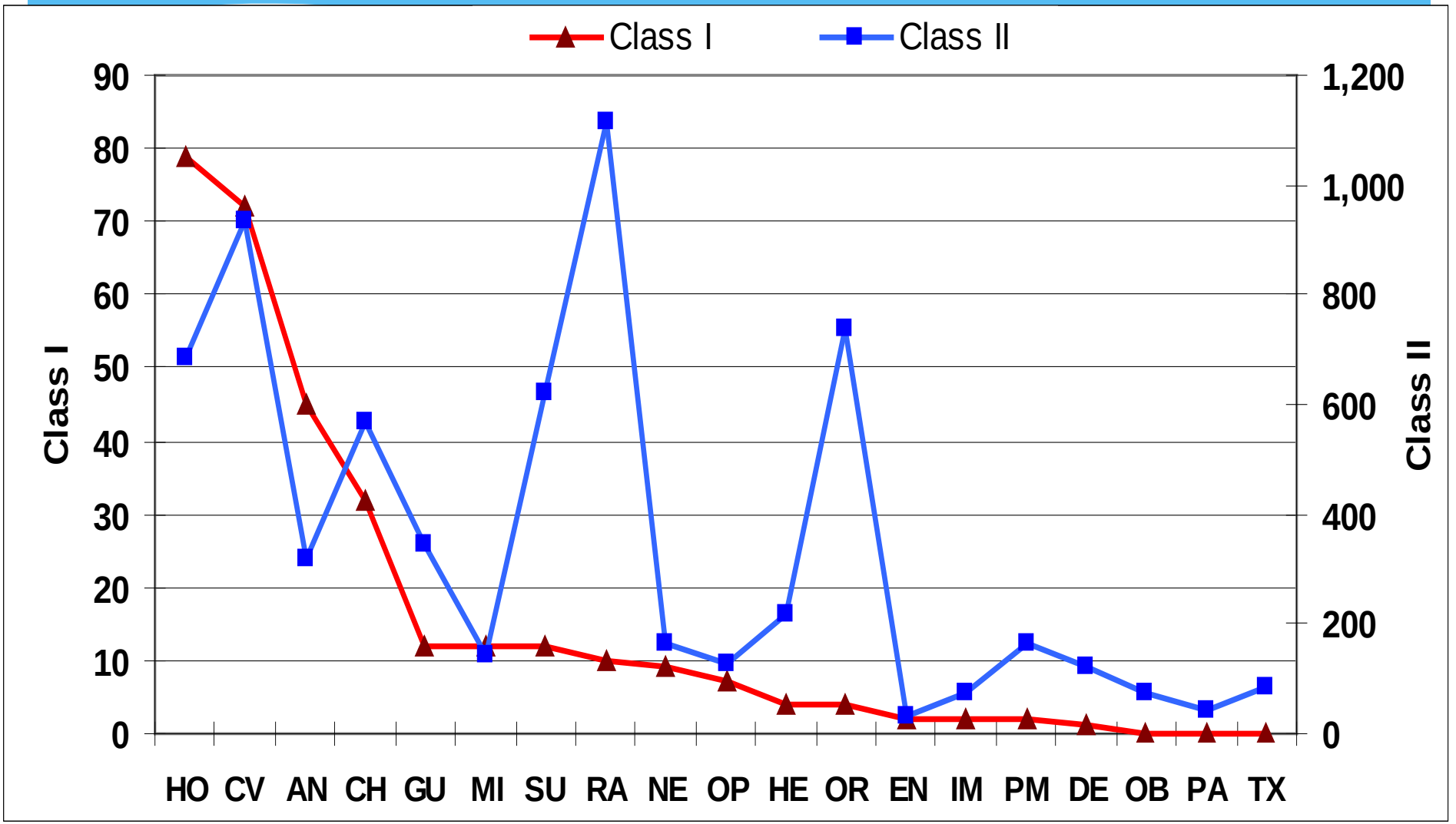
	2003	2004	2005	2006	2007	2008	2009	2010	2011	2012
Class I recall counts	7	24	26	22	27	13	32	49	50	57
All recalls % Class I	1.1%	3.8%	4.5%	3.3%	4.1%	1.6%	4.1%	5.6%	3.9%	4.8%

Has the risk to patients changed?

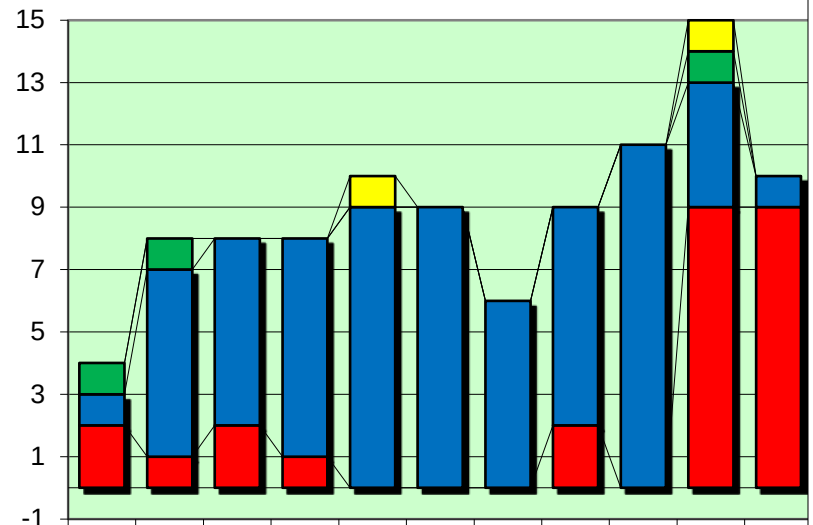




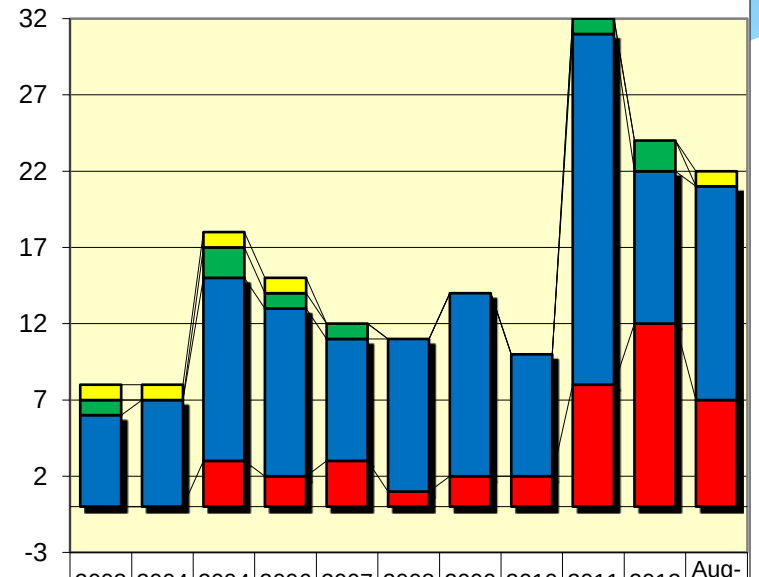
Medical Specialty comparison
Class I vs. Class II



Examples of Class I recall trends: ventilators and infusion pumps



	2003	2004	2004	2006	2007	2008	2009	2010	2011	2012	Aug-13
Safety Alert	0	0	0	0	1	0	0	0	0	1	0
Class III	1	1	0	0	0	0	0	0	0	1	0
Class II	1	6	6	7	9	9	6	7	11	4	1
Class I	2	1	2	1	0	0	0	2	0	9	9

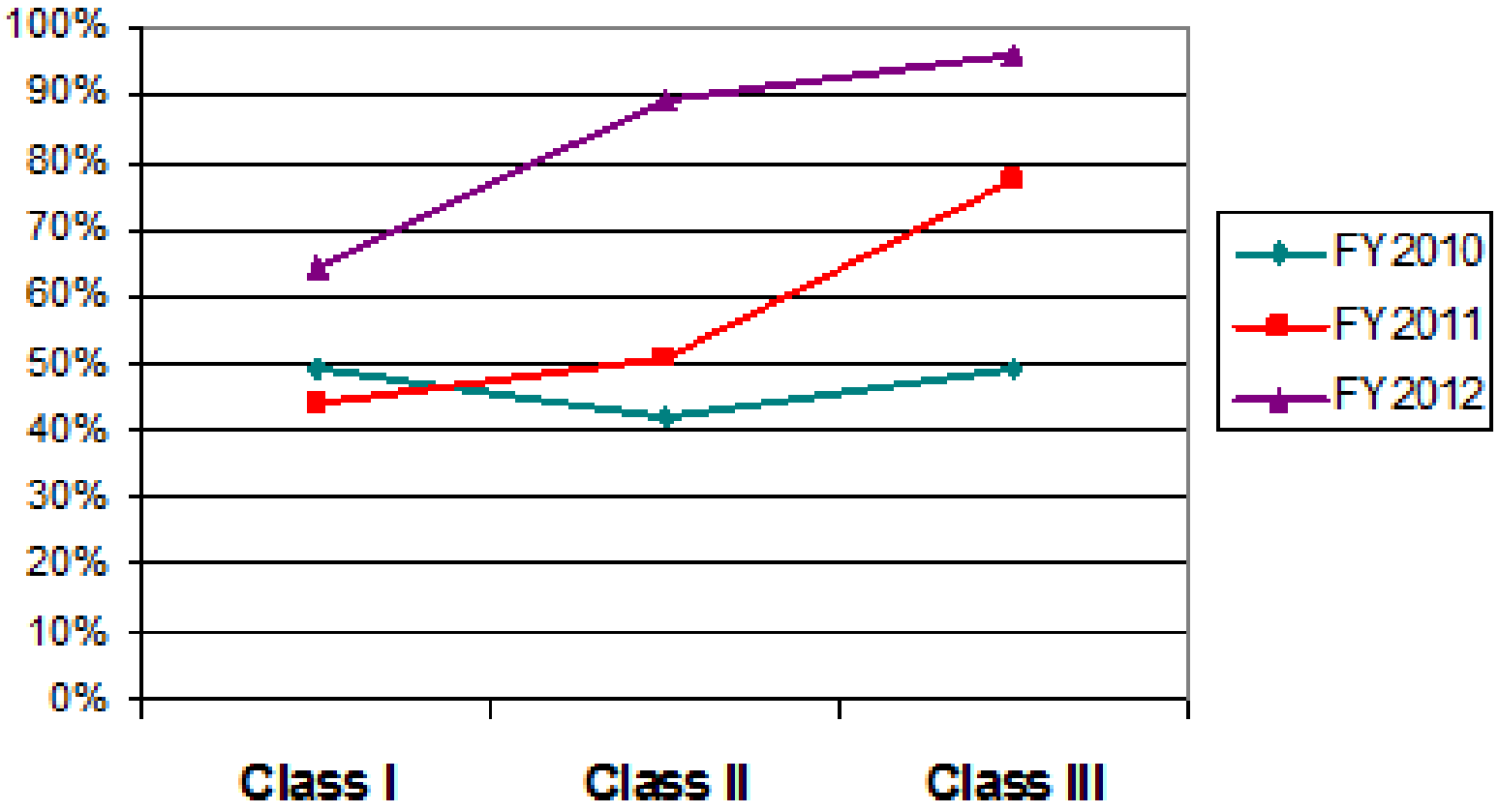


	2003	2004	2004	2006	2007	2008	2009	2010	2011	2012	Aug-13
Safety Alert	1	1	1	1	0	0	0	0	0	0	1
Class III	1	0	2	1	1	0	0	0	1	2	0
Class II	6	7	12	11	8	10	12	8	23	10	14
Class I	0	0	3	2	3	1	2	2	8	12	7

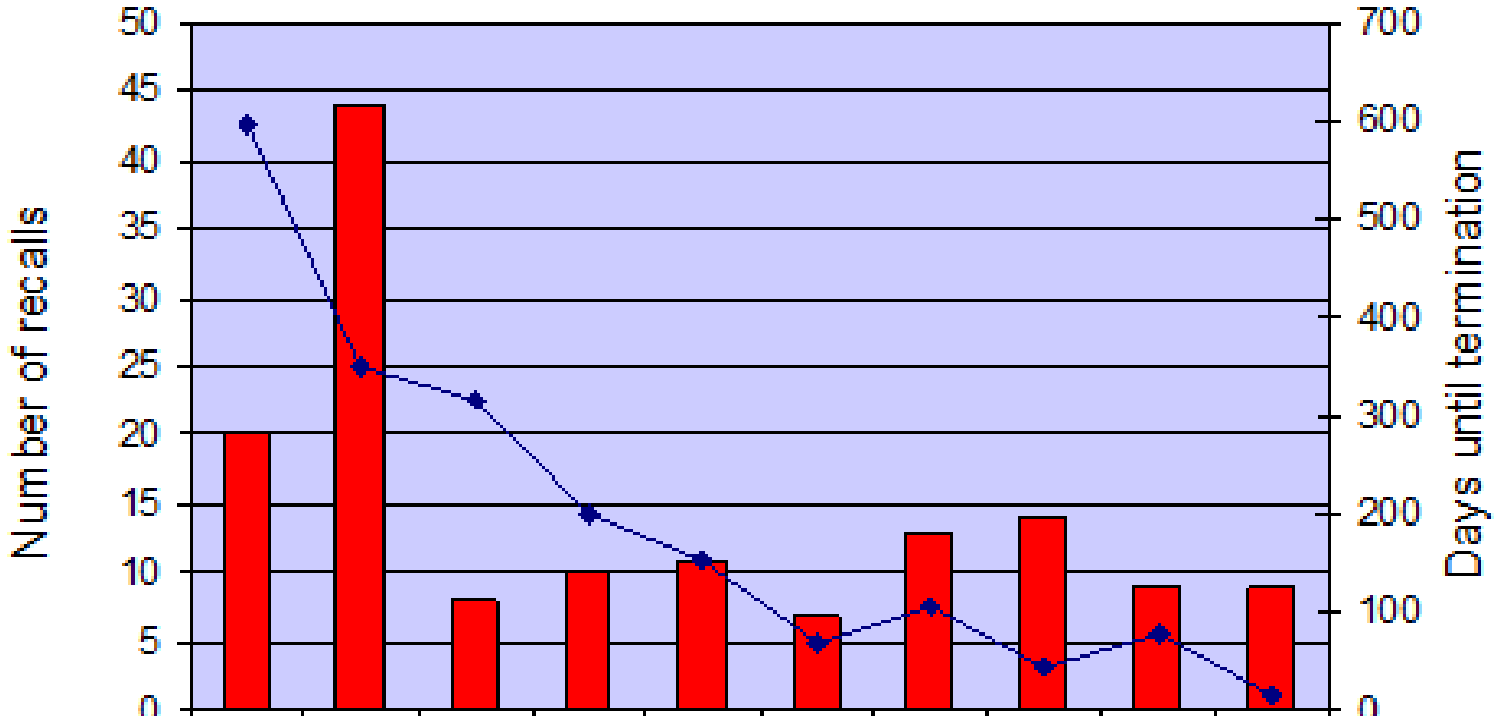
Total Recall Times

Year	Number of Recalls	Phase I - Firm awareness to District awareness (mean days)	Phase II - District awareness until recommendation sent to CDRH (mean days)	Phase III - CDRH receipt to classification and posting (mean days)	Phase I - III total recall days to posting (mean days)
FY2010	876	85.7	99.7	48.3	233.7
FY2011	1,271	98.2	111.6	37.1	246.9
FY2012	1,190	99.4	135.9	21.3	256.6

On Time Rates – FDA Track



Termination Times - CDRH



	FY 2009	FY 2010	FY 2011 Q1	FY 2011 Q2	FY 2011 Q3	FY 2011 Q4	FY 2012 Q1	FY 2012 Q2	FY 2012 Q3	FY 2012 Q4
# Recalls completed	20	44	8	10	11	7	13	14	9	9
Avg days to termination	597	351	317	201	154	68	105	45	77	15

Report conclusions

- **Recalls increased, mostly due to industry growth, enhanced reporting and specific device type initiatives**
- **As demonstrated in device initiative work, FDA and industry can work together to improve device safety for all patients and consumers**
- **Analyzing recall data can inform and support pre/postmarket activities and guide resources as well as provide outreach for external stakeholders**
- **FDA has improved recall process times and communications in spite of increasing numbers**