

Supplementary Online Content

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eTable 1. Origins of currently marketed ICD systems

eTable 2. Mean number of supplements approved per original PMA, by manufacturer

This supplementary material has been provided by the authors to give readers additional information about their work.

eTable 1: Origins of currently marketed ICD systems

Manufacturer	Device Model(s)	PMA Number (Supplement Number)	Supplement Type	Date Approved	Age of PMA at approval (years)
Leads					
Biotronik	Linix Smart	P980023 (S038)	180-Day	9/17/2010	11.9
Boston Scientific	Endotak Reliance G 0174/0175/0176/0177	P910073 (S041)	180-Day	11/4/2003	10.2
Boston Scientific	Endotak Reliance G/SG 0180-0187	P910073 (S043)	Real-Time	3/2/2004	10.5
Medtronic	Sprint Quattro 6944	P920015 (S017)	180-Day	12/15/2000	7.0
Medtronic	Sprint Quattro 6947	P920015 (S024)	Real-Time	11/2/2001	7.9
Medtronic	Sprint Quattro 6935	P920015 (S039)	Real-Time	4/29/2008	14.4
Medtronic	Sprint Quarto 6947M	P920015 (S055)	180-Day	1/9/2012	18.1
Medtronic	Sprint Quattro 6935M	P920015 (S091)	Real-Time	7/2/2012	18.6
St. Jude Medical	Durata 7120/7121/7122	P950022 (S040)	Real-Time	9/6/2007	11.3
St. Jude Medical	Durata 7170/7171	P950022 (S041)	Real-Time	10/16/2007	11.4
St. Jude Medical	Durata 7120Q/7121Q/7122Q	P950022 (S042)	180-Day	1/13/2009	12.7
St. Jude Medical	Durata 7170Q/7171Q	P950022 (S060)	Real-Time	7/10/2009	13.2
Pulse Generators					
Biotronik	Lumax 300/340	P000009 (S020)	180-Day	12/7/2006	6.2
Biotronik	Lumax 540	P000009 (S026)	180-Day	11/4/2008	8.1
Biotronik	Lumax 700/740	P000009 (S047)	180-Day	5/4/2012	11.6
Biotronik	Lumax 540 VR-T DX	P050023 (S029)	Real-Time	4/30/2010	3.7
Biotronik	Lumax 740 VR-T DX	P050023 (S048)	180-Day	5/4/2012	5.7
Boston Scientific	Teligen E102/E110	P960040 (S155)	180-Day	5/8/2008	10.8
Boston Scientific	Energen, Incepta, Punctua	P960040 (S235)	180-Day	11/17/2011	14.3
Medtronic	Secura	P980016 (S114)	180-Day	3/17/2008	9.4
Medtronic	Protecta, Protecta XT	P980016 (S211)	180-Day	3/25/2011	12.5
Sorin Group	Paradym 8250/8550	P980049 (S050)	180-Day	4/7/2010	10.6
Sorin Group	Paradym RF 9250/9550	P980049 (S065)	180-Day	4/10/2012	12.6
St. Jude	Current+ CD1211-36Q	P910023 (S201)	Real-Time	4/8/2009	15.9
St. Jude	Fortify	P910023 (S226)	180-Day	5/7/2010	17.0
St. Jude	Ellipse, Fortify Assura	P910023 (S279)	180-Day	5/7/2012	19.0

ICD = Implantable Cardioverter-Defibrillator; PMA = Pre-Market Approval

eTable 2: Mean number of supplements approved per original PMA, by manufacturer

Manufacturer*	Number of Original PMAs Approved	Mean number of approved supplements per original PMA (standard deviation)	Mean number of approved supplements per original PMA, excluding 30-day notice supplements (standard deviation)
Medtronic	22	114 (99)	49 (45)
Boston Scientific	18	70 (80)	36 (32)
St. Jude Medical	12	104 (89)	71 (53)
Biotronik	6	51 (28)	42 (23)
Sorin	5	40 (31)	22 (18)
Pacesetter	4	27 (32)	13 (14)
Teleelectronics	3	12 (16)	11 (16)
Guidant	2	50 (46)	9 (8)
Cardiac Control Systems	2	14 (3)	14 (3)
Cameron Health	1	1	0
Angeion	1	4	4
Cook Pacemaker	1	10	10
All Manufacturers	77	76 (82)	40 (40)

*Each PMA is assigned to the manufacturer that submitted its most recent supplement. Many PMAs changed ownership over time as manufacturers merged (*e.g.*, Boston Scientific acquired Guidant), so the supplements for a given original PMA may have actually been submitted by several different manufacturers.