

IVD mTFR	DA-2015-03642-1	20-May-15	26-Aug-15	2015	10-Jun-15	60	43	77
IVD mTFR	DA-2015-03643-1	20-May-15	26-Aug-15	2015	10-Jun-15	60	43	77
IVD mTFR	DA-2015-03644-1	20-May-15	26-Aug-15	2015	10-Jun-15	60	43	77
IVD mTFR	DA-2015-03739-1	25-May-15	16-Jul-15	2015	02-Jun-15	60	11	44
IVD mTFR	DA-2015-03827-1	28-May-15	24-Jul-15	2015	16-Jun-15	60	23	38
IVD mTFR	DA-2015-03828-1	28-May-15	24-Jul-15	2015	16-Jun-15	60	23	38
IVD mTFR	DA-2015-03830-1	29-May-15	26-Aug-15	2015	05-Jun-15	60	48	82
IVD mTFR	DA-2015-03879-1	29-May-15	05-Aug-15	2015	09-Jun-15	60	28	57
IVD mTFR	DA-2015-03920-1	01-Jun-15	28-Jul-15	2015	16-Jun-15	60	21	42
IVD mTFR	DA-2015-03921-1	01-Jun-15	31-Jul-15	2015	16-Jun-15	60	23	45
IVD mTFR	DA-2015-03922-1	01-Jun-15	14-Jul-15	2015	16-Jun-15	60	10	28
IVD mTFR	DA-2015-03923-1	01-Jun-15	14-Jul-15	2015	16-Jun-15	60	11	28
IVD mTFR	DA-2015-03924-1	01-Jun-15	07-Aug-15	2015	23-Jun-15	60	40	45
IVD mTFR	DA-2015-03943-1	02-Jun-15	17-Sep-15	2015	24-Jun-15	60	40	85
IVD mTFR	DA-2015-03944-1	02-Jun-15	17-Sep-15	2015	24-Jun-15	60	39	85
IVD mTFR	DA-2015-03945-1	02-Jun-15	17-Sep-15	2015	24-Jun-15	60	40	85
IVD mTFR	DA-2015-03946-1	02-Jun-15	17-Sep-15	2015	24-Jun-15	60	39	85
IVD mTFR	DA-2015-03947-1	02-Jun-15	09-Oct-15	2015	24-Jun-15	60	53	107
IVD mTFR	DA-2015-03948-1	02-Jun-15	17-Sep-15	2015	24-Jun-15	60	40	85
IVD mTFR	DA-2015-03979-1	03-Jun-15	27-Jul-15	2015	11-Jun-15	60	17	46
IVD mTFR	DA-2015-04030-1	04-Jun-15	20-Jul-15	2015	22-Jun-15	60	21	28
IVD mTFR	DA-2015-04032-1	04-Jun-15	20-Jul-15	2015	22-Jun-15	60	21	28
IVD mTFR	DA-2015-04035-1	05-Jun-15	06-Aug-15	2015	11-Jun-15	60	26	56
IVD mTFR	DA-2015-04039-1	04-Jun-15	13-Aug-15	2015	23-Jun-15	60	29	51
IVD mTFR	DA-2015-04040-1	04-Jun-15	13-Aug-15	2015	15-Jun-15	60	27	59
IVD mTFR	DA-2015-04041-1	04-Jun-15	13-Aug-15	2015	15-Jun-15	60	27	59
IVD mTFR	DA-2015-04043-1	04-Jun-15	14-Aug-15	2015	11-Jun-15	60	17	64
IVD mTFR	DA-2015-04143-1	04-Jun-15	28-Aug-15	2015	15-Jun-15	60	40	74
IVD mTFR	DA-2015-04200-1	09-Jun-15	24-Aug-15	2015	23-Jun-15	60	34	62
IVD mTFR	DA-2015-04240-1	10-Jun-15	16-Oct-15	2015	15-Jun-15	60	33	123
IVD mTFR	DA-2015-04242-1	10-Jun-15	10-Sep-15	2015	15-Jun-15	60	46	87
IVD mTFR	DA-2015-04273-1	11-Jun-15	13-Aug-15	2015	15-Jun-15	60	23	59
IVD mTFR	DA-2015-04281-1	11-Jun-15	22-Sep-15	2015	15-Jun-15	60	7	99
IVD mTFR	DA-2015-04356-1	12-Jun-15	21-Aug-15	2015	19-Jun-15	60	34	63
IVD mTFR	DA-2015-04359-1	12-Jun-15	28-Aug-15	2015	26-Jun-15	60	39	63
IVD mTFR	DA-2015-04360-1	12-Jun-15	28-Aug-15	2015	26-Jun-15	60	42	63
IVD mTFR	DA-2015-04387-1	15-Jun-15	21-Sep-15	2015	26-Jun-15	60	49	87

IVD mTFR	DA-2015-04390-1	15-Jun-15	04-Aug-15	2015	26-Jun-15	60	11	39
IVD mTFR	DA-2015-04391-1	15-Jun-15	03-Aug-15	2015	26-Jun-15	60	12	38
IVD mTFR	DA-2015-04426-1	16-Jun-15	03-Sep-15	2015	25-Jun-15	60	54	70
IVD mTFR	DA-2015-04637-1	22-Jun-15	06-Nov-15	2015	25-Jun-15	60	58	134
IVD mTFR	DA-2015-04669-1	23-Jun-15	17-Aug-15	2015	21-Jul-15	60	23	27
IVD mTFR	DA-2015-04679-1	23-Jun-15	09-Sep-15	2015	25-Jun-15	60	35	76
IVD mTFR	DA-2015-04722-1	24-Jun-15	16-Nov-15	2015	01-Jul-15	60	85	138
IVD mTFR	DA-2015-04723-1	24-Jun-15	21-Oct-15	2015	30-Jun-15	60	42	113
IVD mTFR	DA-2015-04725-1	24-Jun-15	16-Nov-15	2015	01-Jul-15	60	84	138
IVD mTFR	DA-2015-04726-1	24-Jun-15	28-Aug-15	2015	30-Jun-15	60	11	59
IVD mTFR	DA-2015-04727-1	24-Jun-15	23-Nov-15	2015	30-Jun-15	60	59	146
IVD mTFR	DA-2015-04807-1	25-Jun-15	30-Oct-15	2015	20-Jul-15	60	63	102
IVD mTFR	DA-2015-04808-1	25-Jun-15	28-Oct-15	2015	20-Jul-15	60	57	100
IVD mTFR	DA-2015-04809-1	25-Jun-15	30-Oct-15	2015	20-Jul-15	60	60	102
IVD mTFR	DA-2015-04810-1	25-Jun-15	30-Nov-15	2015	30-Jun-15	60	93	153
IVD mTFR	DA-2015-04811-1	01-Jun-15	31-Aug-15	2015	01-Jul-15	60	40	61
IVD mTFR	DA-2015-04813-1	25-Jun-15	30-Oct-15	2015	20-Jul-15	60	59	102
IVD mTFR	DA-2015-04822-1	25-Jun-15	17-Sep-15	2015	30-Jun-15	60	41	79
IVD mTFR	DA-2015-04823-1	25-Jun-15	17-Sep-15	2015	30-Jun-15	60	45	79
IVD mTFR	DA-2015-04856-1	26-Jun-15	02-Sep-15	2015	01-Jul-15	60	23	63
IVD mTFR	DA-2015-04857-1	26-Jun-15	16-Nov-15	2015	21-Jul-15	60	75	118
IVD mTFR	DA-2015-04858-1	26-Jun-15	16-Nov-15	2015	21-Jul-15	60	75	118
IVD mTFR	DA-2015-04859-1	26-Jun-15	16-Nov-15	2015	21-Jul-15	60	75	118
IVD mTFR	DA-2015-04862-1	26-Jun-15	14-Sep-15	2015	30-Jun-15	60	34	76
IVD mTFR	DA-2015-04868-1	26-Jun-15	23-Sep-15	2015	30-Jun-15	60	43	85
IVD mTFR	DA-2015-04961-1	29-Jun-15	18-Sep-15	2015	23-Jul-15	60	50	57
IVD mTFR	DA-2015-05159-1	30-Jun-15	06-Aug-15	2015	24-Jul-15	60	20	13
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IVD mTFR	DA-2015-05168-1	30-Jun-15	23-Dec-15	2015	24-Jul-15	60	91	152
IVD mTFR	DA-2015-05169-1	30-Jun-15	21-Oct-15	2015	21-Jul-15	60	59	92
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IVD mTFR	DA-2015-05171-1	30-Jun-15	21-Oct-15	2015	21-Jul-15	60	59	92
IVD mTFR	DA-2015-05172-1	30-Jun-15	14-Sep-15	2015	24-Jul-15	60	41	52
IVD mTFR	DA-2015-05173-1	30-Jun-15	15-Sep-15	2015	24-Jul-15	60	40	53
IVD mTFR	DA-2015-05190-1	30-Jun-15	03-Dec-15	2015	24-Jul-15	60	74	132
IVD mTFR	DA-2015-05258-1	01-Jul-15	23-Oct-15	2015	27-Jul-15	60	73	88
IVD mTFR	DA-2015-05293-1	02-Jul-15	02-Nov-15	2015	28-Jul-15	60	65	97

IVD mTFR	DA-2015-05646-1	15-Jul-15	30-Sep-15	2015	30-Jul-15	60	41	62
IVD mTFR	DA-2015-05647-1	15-Jul-15	28-Oct-15	2015	04-Aug-15	60	71	85
IVD mTFR	DA-2015-05648-1	15-Jul-15	30-Sep-15	2015	30-Jul-15	60	42	62
IVD mTFR	DA-2015-05649-1	15-Jul-15	30-Sep-15	2015	30-Jul-15	60	42	62
IVD mTFR	DA-2015-05774-1	17-Jul-15	02-Nov-15	2015	29-Jul-15	60	55	96
IVD mTFR	DA-2015-05866-1	21-Jul-15	05-Nov-15	2015	27-Jul-15	60	55	101
IVD mTFR	DA-2015-05867-1	21-Jul-15	06-Nov-15	2015	04-Aug-15	60	61	94
IVD mTFR	DA-2015-06157-1	31-Jul-15	10-Nov-15	2015	07-Aug-15	60	47	95
IVD mTFR	DA-2015-06216-1	04-Aug-15	20-Nov-15	2015	14-Aug-15	60	67	98
IVD mTFR	DA-2015-06217-1	04-Aug-15	20-Nov-15	2015	14-Aug-15	60	65	98
IVD mTFR	DA-2015-06218-1	04-Aug-15	23-Nov-15	2015	14-Aug-15	60	68	101
IVD mTFR	DA-2015-06219-1	04-Aug-15	24-Nov-15	2015	14-Aug-15	60	68	102
IVD mTFR	DA-2015-06293-1	09-Aug-15	16-Dec-15	2015	17-Aug-15	60	67	121
IVD mTFR	DA-2015-06535-1	19-Aug-15	18-Sep-15	2015	21-Aug-15	60	17	28
IVD mTFR	DA-2015-06677-1	21-Aug-15	17-Dec-15	2015	31-Aug-15	60	61	108
IVD mTFR	DA-2015-06990-1	07-Sep-15	10-Dec-15	2015	11-Sep-15	60	37	90
IVD mTFR	DA-2015-07013-1	08-Sep-15	09-Nov-15	2015	23-Sep-15	60	39	47
IVD mTFR	DA-2015-07014-1	08-Sep-15	09-Nov-15	2015	23-Sep-15	60	39	47
IVD mTFR	DA-2015-07699-1	01-Oct-15	24-Dec-15	2015	13-Oct-15	60	30	72
IVD mTFR	DA-2015-07725-1	06-Oct-15	24-Nov-15	2015	13-Oct-15	60	13	42
IVD mTFR	DA-2015-07754-1	08-Oct-15	22-Dec-15	2015	30-Oct-15	60	34	53
IVD mTFR	DA-2015-08400-1	09-Nov-15	10-Dec-15	2015	20-Nov-15	60	11	20
IVD mTFR	DA-2015-08662-1	20-Nov-15	08-Dec-15	2015	25-Nov-15	60	3	13
<b>IVD mTFR</b>	<b>571</b>							

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# FDA - PMA Expedited Reviews

Source: FDA PMA Approval dB (<http://www.accessdata.fda>)

PRODUCT	COMPANY	APPROVAL DA	PMA NUMBER	Expedited assessment
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## PMA expedited reviews -all

Total Count:

19

6/03/2015	P110024	Yes
03/17/2010	P090018	Yes
8/04/2011	P100034	Yes
6/04/2011	P100018	Yes
4/04/2012	P020018/S040	Yes
04/27/2010	P080032	Yes
3/05/2013	P080009	Yes
05/28/2014	P100045	Yes
1/07/2010	P050034	Yes
08/26/2011	P110012	Yes
09/16/2010	P010012/S230	Yes
09/28/2012	P110042	Yes
10/18/2012	P110039	Yes
10/24/2013	P100009	Yes
10/19/2012	P110021	Yes
2/11/2011	P100041	Yes
1/11/2011	P090012	Yes
12/14/2011	P100046	Yes
12/27/2012	P110014	Yes

## 2015 - All PMA Approvals

Total Expedited Reviews:

1 / 2132

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6/03/2015	P110024	Yes
1/09/2015	P010012/S381	No
01/14/2015	P000012/S051	No
01/14/2015	P050028/S043	No
01/14/2015	P060030/S044	No
01/14/2015	P100023/S112	No
01/14/2015	P110010/S101	No

01/14/2015	P110037/S017	No
01/14/2015	P120006/S017	No
01/14/2015	P120010/S051	No
01/14/2015	P130019	No
01/14/2015	P130025	No
01/14/2015	P130030/S007	No
01/14/2015	P980022/S175	No
1/02/2015	P120010/S049	No
1/02/2015	P980022/S174	No
1/08/2015	P040037/S074	No
1/08/2015	P130006/S014	No
1/08/2015	P910001/S076	No
1/08/2015	P960042/S051	No
1/07/2015	P000006/S039	No
1/07/2015	P050017/S009	No
1/07/2015	P100022/S010	No
1/07/2015	P120010/S050	No
1/07/2015	P910001/S075	No
01/13/2015	P030035/S129	No
01/13/2015	P030053/S023	No
01/13/2015	P030054/S278	No
01/13/2015	P100022/S011	No
01/13/2015	P880086/S251	No
01/13/2015	P910023/S348	No
1/12/2015	P020002/S009	No
1/12/2015	P120016/S005	No
1/12/2015	P860057/S130	No
1/09/2015	P040044/S060	No
1/09/2015	P040044/S061	No
1/09/2015	P080011/S028	No
1/09/2015	P120016/S008	No
1/09/2015	P120020/S006	No
1/09/2015	P780007/S053	No

1/09/2015	P890023/S021	No
1/09/2015	P960040/S340	No
01/21/2015	P010012/S380	No
01/21/2015	P010029/S021	No
01/21/2015	P010031/S479	No
01/21/2015	P030017/S211	No
01/21/2015	P060001/S020	No
01/21/2015	P060038/S022	No
01/21/2015	P080011/S033	No
01/21/2015	P100014/S017	No
01/21/2015	P100023/S104	No
01/21/2015	P100033/S002	No
01/21/2015	P100049/S011	No
01/21/2015	P120009/S002	No
01/21/2015	P830055/S154	No
01/21/2015	P980016/S515	No
01/16/2015	P020056/S029	No
01/16/2015	P030053/S019	No
01/16/2015	P040045/S048	No
01/16/2015	P100026/S027	No
01/16/2015	P110027/S003	No
01/16/2015	P120022/S005	No
01/16/2015	P840001/S287	No
01/15/2015	P000012/S052	No
01/15/2015	P020025/S066	No
01/15/2015	P090022/S024	No
01/15/2015	P110020/S012	No
01/15/2015	P110027/S002	No
01/15/2015	P110037/S018	No
01/15/2015	P120019/S005	No
01/15/2015	P120022/S004	No
01/15/2015	P130030/S008	No
01/15/2015	P890055/S059	No



01/15/2015	P960016/S052	No
01/29/2015	P010012/S376	No
01/29/2015	P120010/S042	No
01/29/2015	P120010/S053	No
01/29/2015	P140010/S001	No
01/29/2015	P960040/S336	No
01/29/2015	P980022/S167	No
01/22/2015	N18033/S075	No
01/23/2015	P110016/S013	No
01/23/2015	P120005/S028	No
01/23/2015	P130016/S010	No
01/23/2015	P970051/S127	No
01/22/2015	P020004/S110	No
01/22/2015	P040043/S071	No
01/22/2015	P040045/S049	No
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12/22/2015	P140020/S004	No

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12/18/2015	P140009/S005	No
12/18/2015	P910001/S082	No
12/18/2015	P970003/S182	No
12/18/2015	P980037/S054	No
12/23/2015	P080025/S103	No
12/23/2015	P120010/S080	No
12/23/2015	P130017/S005	No

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**Total Expedited Reviews:**

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05/28/2014	P100045	Yes
02/27/2014	P010031/S422	No
02/25/2014	P100026/S010	No
02/21/2014	P100026/S009	No
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1/08/2014	P090013/S121	No
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1/08/2014	P830061/S102	No
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1/08/2014	P960058/S105	No
1/08/2014	P980035/S356	No
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01/14/2014	P110019/S055	No
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01/14/2014	P910001/S069	No
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02/18/2014	P910023/S327	No
02/18/2014	P980016/S457	No
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02/18/2014	P980035/S364	No
02/14/2014	P980035/S343	No
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12/30/2014	P110029/S020	No
12/30/2014	P140010	No

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3/05/2013	P080009	Yes
10/24/2013	P100009	Yes
02/28/2013	P010031/S352	No
1/02/2013	P050028/S028	No
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	09/28/2012	P110042	Yes
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	12/27/2012	P110014	Yes
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**2011 - All PMA Approvals**

**Total Expedited Reviews:**

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**0.27%**

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11/22/2011	P980035/S245	No
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11/10/2011	P020004/S062	No
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11/10/2011	P040042/S023	No
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11/17/2011	P100032/S004	No
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11/17/2011	P850051/S078	No
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11/17/2011	P990012/S011	No
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11/15/2011	P930038/S069	No
11/15/2011	P940035/S006	No

11/15/2011	P990038/S014	No
11/15/2011	P990041/S013	No
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11/15/2011	P990044/S011	No
11/15/2011	P990045/S011	No
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11/16/2011	P090007/S004	No
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11/16/2011	P090009/S004	No
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11/16/2011	P100032/S002	No
11/16/2011	P990012/S010	No
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12/07/2011	P890003/S239	No
12/07/2011	P950020/S047	No
12/07/2011	P990034/S026	No
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12/06/2011	P980035/S249	No
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11/22/2011	P110010	No
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11/23/2011	P030054/S204	No
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12/05/2011	P030005/S080	No



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12/05/2011	P900056/S111	No
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12/05/2011	P980003/S033	No
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12/01/2011	P050042/S014	No
12/01/2011	P060035/S012	No
12/01/2011	P080023/S010	No
12/01/2011	P910023/S280	No
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12/20/2011	P090022/S007	No
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12/20/2011	P960016/S038	No

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12/20/2011	P980022/S075	No
12/20/2011	P980022/S099	No
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12/15/2011	P040045/S030	No
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12/15/2011	P860004/S136	No
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12/13/2011	P010031/S281	No
12/13/2011	P040012/S043	No
12/13/2011	P060006/S023	No
12/13/2011	P060025/S008	No
12/13/2011	P090013/S045	No
12/13/2011	P980016/S328	No
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12/12/2011	P040036/S027	No
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12/12/2011	P060038/S010	No
12/12/2011	P080014/S007	No
12/12/2011	P840001/S198	No
12/12/2011	P860004/S162	No
12/12/2011	P860057/S081	No
12/12/2011	P870056/S044	No
12/12/2011	P870077/S040	No
12/12/2011	P960009/S132	No
12/12/2011	P980049/S067	No
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12/22/2011	P050049/S009	No
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12/21/2011	P020004/S067	No
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12/21/2011	P060035/S013	No
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12/19/2011	P830061/S074	No
12/19/2011	P850089/S086	No
12/19/2011	P890003/S241	No
12/19/2011	P920015/S085	No
12/19/2011	P930039/S065	No
12/19/2011	P950024/S039	No
12/19/2011	P980050/S069	No
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12/29/2011	P050028/S019	No
12/29/2011	P060030/S020	No
12/29/2011	P100020/S001	No
12/29/2011	P970055/S012	No
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12/23/2011	P010012/S273	No
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12/23/2011	P010031/S285	No
12/21/2011	P890003/S242	No
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12/21/2011	P910007/S033	No
12/21/2011	P920014/S031	No

12/21/2011	P980007/S024	No
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12/21/2011	P990071/S013	No
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12/30/2011	P030035/S091	No
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12/28/2011	P950032/S066	No
12/28/2011	P960009/S133	No
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12/23/2011	P040036/S028	No
12/23/2011	P060037/S015	No
12/23/2011	P900061/S109	No
12/23/2011	P930029/S035	No
12/23/2011	P940008/S028	No
12/23/2011	P950005/S036	No
12/23/2011	P970003/S142	No
12/23/2011	P980016/S332	No
12/23/2011	P980035/S254	No

.gov/scripts/cdrh/cfdocs/cfPMA/pma.cfm)

	<b>Expedited</b>	<b>Total</b>	<b>Proportion</b>
<b>Total</b>	<b>15</b>	<b>11579</b>	<b>0.13% (5 year average - 2011-2015)</b>
2015	1	2132	0.05%
2014	1	2479	0.04%
2013	2	2338	0.09%
2012	5	2407	0.21%
2011	6	2223	0.27%

## PATHWAY 3

### Assumptions and Limitations:

There are countless potential models for expedited approval, in both conformity assessment and application for inclusion work streams.

The details below are for expedited applications for inclusion in the ARTG, assuming:

- applicant holds CA certification from EU (or suitable other regulator approval, such as FDA PMA)
- applicant able to fully comply with Australian regulatory requirements (eg Essential Principles)
- application for a product which would otherwise be subject to compulsory audit (Level 2)

This approach could be implemented without legislative or significant regulatory amendment. Business process design (pre-assessment screening process, as

This is quite different from the FDA model, which involved detailed support through the product development lifecycle (very resource intensive, unlikely to b

Assumption that conformity assessment evidence held in another jurisdiction reflects reality of product development (products not typically commercialised

### Estimated timeframes for expedited approval

**Working days      Calendar days**

Application subject to a pre-screening process to quality as 'new and novel'	-20	-28
Application submitted on 'expedited form' with associated evidence		
- saves up to 20 days typical for 'selection for audit'	20	28 Note: actual time may
- saves up to 20 days typical for applicant to provide audit data	20	28 Note: actual time may
- saves 50% of assessment time (top of queue for assessments)	75	105 Note: assumption only
2015 average Level 2 audit timeframe (duration - selection for audit to completion)	171	239 Actual average duratio
<b>Net saving</b>	<b>95</b>	<b>133</b>
<b>Net duration for completion of application</b>	<b>75</b>	<b>105</b>
<i>(Comparison - duration for normal application)</i>	<i>191</i>	<i>267</i>

### Estimated administrative timesaving for applicant for expedited approval

Additional time required for pre-screening process	2	* Note: assumption that
Savings for assessment process	0	* Note: assumption that
		* Calendar days not ca

assessment process) and IT support (new application form) would be required.

(not viable in the Australian context)

(not in Australian market, extensive clinical testing rarely undertaken only in Australia, etc)

could be less than 20 days - 20 days is the statutory timeframe during which TGA must either include the device in the ARTG or select for audit

could be less or more than 20 days - 20 days is the default timeframe provided for sponsors to provide additional audit information. They may do this inside the 20 day:

- actual times which vary widely depending on application, such as which and how many assessments are required (eg review of information, technical reviews such as clinical data) (from selection for audit to completion of applications - includes both TGA and sponsor time)

applicant can offset some of the data gathering to support pre-screening in assessment process (same information), however the process itself will take additional time

applicant is complying with existing assessment process - still needs to provide all existing requirements (just shifting this process to the front end of the assessment process)

time calculated for sponsor administrative time - calendar days are relevant to delay cost rather than administrative costs



s, and may ask for an extension of time. Assessment will commence on receipt of information.  
ch as clinical evidence, microbiology, etc)

al time. Estimated at 2 working days additional time (net with assessment process)  
rent)