

Medical Device Fees for FY 2012

Application fee type	Standard Fee, as a Percent of the standard fee for a premarket application	FY 2012 standard fee	FY 2012 small business fee
Premarket application (a PMA submitted under section 515(c)(1) of the FD&C Act (21 U.S.C. 360e(c)(1)), a PDP submitted under section 515(f) of the FD&C Act, or a BLA submitted under section 351 of the Public Health Service (PHS) Act (42 U.S.C. 262)).	Set in statute at \$256,382, but offset by multiplying by 85.8281 percent.	\$220,050	\$55,013
Premarket report (submitted under section 515(c)(2) of the FD&C Act).	100%.....	220,050	55,013
Efficacy supplement (to an approved BLA under section 351 of the PHS Act).	100%.....	220,050	55,013
Panel-track supplement.....	75%.....	165,038	41,259
180-day supplement.....	15%.....	33,008	8,252
Real-time supplement.....	7%.....	15,404	3,851
510(k) premarket notification submission.....	1.84%.....	4,049	2,024
30-day notice.....	1.6%.....	3,521	1,760
513(g) (21 U.S.C. 360c(g)) request for classification information.	1.35%.....	2,971	1,485
Annual Fee Type			
Annual fee for periodic reporting on a class III device.	3.5%.....	7,702	1,925
Annual establishment registration fee (to be paid by each establishment that is a manufacturer, a single-use device reprocessor, or a specification developer, as defined by 21 U.S.C. 379i(13)).	Set in statute at \$2,364, but offset by multiplying by 85.8281 percent.	2,029	2,029