Medical Device User Fee Rates for Fiscal Year 2019

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The Food and Drug Administration (FDA) is announcing the fee rates and payment procedures for medical device user fees for fiscal year (FY) 2019. The Federal Food, Drug, and Cosmetic Act (FD&C Act), as amended by the Medical Device User Fee Amendments of 2017 (MDUFA IV), authorizes FDA to collect user fees for certain medical device submissions and annual fees both for certain periodic reports and for establishments subject to registration. This notice establishes the fee rates for FY 2019, which apply from **October 1, 2018**, through **September 30, 2019**.

Background

Section 738 of the FD&C Act (21 U.S.C. 379j) establishes fees for certain medical device applications, submissions, supplements, notices, and requests, for periodic reporting on class III devices; and for the registration of certain establishments. Under statutorily defined conditions, a qualified applicant may receive a fee waiver or may pay a lower small business fee.

If your business, including your affiliates, has gross receipts or sales of no more than $100 million for the most recent tax year, you may qualify for reduced small business fees. If your business, including your affiliates, has gross sales or receipts of no more than $30 million, you may also qualify for a waiver of the fee for your first premarket application (i.e. PMA, PDP, or BLA) or premarket report. If you want to pay the small business fee rate for a submission or you want to receive a waiver of the fee for your first premarket application or premarket report, you should submit the materials showing you qualify as a small business at least 60 days before you send your submission to FDA.

Medical Device Fees from 2016 to 2019 – Standard Fees

Application Fee Type	2019 (USD)	2018 (USD)	2017 (USD)	2016 (USD)
510(k) Premarket Notification Submission	$10,953	$10,566	$4,690	$5,228
513(g) request for classification information	$4,349	$4,195	$3,166	$3,529
PMA/PDP/PMR/BLA	$322,147	$310,764	$234,495	$216,388
Panel-track Supplement	$241,610	$233,073	$175,871	$191,041
180-day Supplement	$48,322	$46,615	$35,174	$39,208
Real-time Supplement	$22,550	$21,753	$16,415	$18,297
BLA Efficacy Supplement	$322,147	$310,764	$234,495	$216,388
PMA Annual Report	$11,275	$10,877	$8,207	$9,149
30-day Notice	$5,154	$4,972	$3,752	$4,182
De Novo classification request	$96,644	$93,229	N/A	N/A
Annual Establishment Registration	$4,884	$4,624	$3,382	$3,845

Medical Device Fees from 2019 to 2016 – Small Business Fee

Application Fee Type	2019 (USD)	2018 (USD)	2017 (USD)	2016 (USD)
510(k) Premarket Notification Submission	$2,738	$2,642	$2,345	$2,614
513(g) request for classification information	$2,175	$2,098	$1,583	$1,765
PMA/PDP/PMR/BLA	$80,537	$77,691	$58,624	$65,347
Panel-track Supplement	$60,403	$58,268	$43,968	$49,010
180-day Supplement	$12,081	$11,654	$8,794	$9,802
Real-time Supplement	$5,638	$5,438	$4,104	$4,574
BLA Efficacy Supplement	$80,537	$77,691	$58,624	$65,347
PMA Annual Report	$2,819	$2,719	$2,052	$2,287
30-Day Notice	$2,577	$2,486	$1,876	$2,091
De Novo classification request	$24,161	$23,367	N/A	N/A
Annual Establishment Registration	$4,884	$4,624	$3,382	$3,845

Medical Device Fees Evaluation

The FDA medical device user fees will increase by about four percent for the agency's 2019 fiscal year. The latest FDA user fee increases are much less substantial than those put in place last year. The FY 2019 revenue from adjusted fee is projected to be $ 207,708,611.

The medical device user fee rates for the fiscal year 2018 were significantly increased by 33% or more (under the Medical Device User Fee Amendments of 2017 (MDUFA IV)). The standard fee for 510(k) premarket notification submissions increased around 125% (from $4,690 to $10,566). The FDA created the De Novo applications fee for the first-time last year.

The FDA's medical device registration user fees for the agency's 2017 fiscal year decreased nearly across the board, including 10% reductions for 510(k) premarket notifications. The 2017 user fee reductions stem from offset provisions of the Federal Food, Drug & Cosmetic Act, which came into effect after the FDA reported fee collections that exceeded appropriated cumulative amounts between the regulator's 2013 and 2016 fiscal years. As a result, the "excess shall be credited to the appropriation account of the FDA and shall be subtracted from the amount of fees that would otherwise be authorized to be collected for FY 2017," states the FDA's notice on its 2017 user fees.

Reference:
Medical Device User Fee Rates for Fiscal Year 2019 - Docket No. FDA–2017–N–0007
FDA and Emergo's web sites