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Medical Device User Fee Amendments (MDUFA)


An official website of the United States government

User Fees for Fy2022

Annual Establishment Registration Fee: $5,672
All establishments must pay the establishment registration fee. There are no waivers or reductions for small establishments, businesses, or groups.

Other fees for Fiscal Year 2022 (October 1, 2021 through September 30, 2022) are:

APPLICATION TYPE	STANDARD FEE	SMALL BUSINESS FEE†
510(k)	$12,745	$3,186
513(g)	$5,061	$2,530
PMA,PDP,PMR,BLA	$374,858	$93,714
De Novo Classification Request	$112,457	$28,114
Panel-track Supplement	$281,143	$70,286
180-Day Supplement	$56,229	$14,057
Real-Time Supplement	$26,240	$6,560
BLA Efficacy Supplement	$374,858	$93,714
30-Day Notice	$5,998	$2,999
Annual Fee for Periodic Reporting on a Class III device (PMAs,PDPs, and PMRs)	$13,120	$3,280

*† **Small Business Fee:** For businesses certified by the Center for Devices and Radiological Health (CDRH) as a small business..*
*‡ **510(k) Fees:** All types of 510(k)s (Traditional, Abbreviated, and Special) are subject to the user fee. However, there is no user fee for 510(k)s submitted to the FDA on behalf of an FDA-accredited third-party reviewer.*