

FY 2021 MDUFA User Fees

The Fees for Fiscal Year 2021 (October 1, 2020 through September 30, 2021) are as follows:

APPLICATION TYPE	STANDARD FEE	SMALL BUSINESS FEE†
510(k)‡	\$12,432	\$3,108
513(g)	\$4,936	\$2,468
PMA, PDP, PMR, BLA	\$365,657	\$91,414
De Novo Classification Request	\$109,697	\$27,424
Panel-track Supplement	\$274,243	\$68,561
180-Day Supplement	\$54,849	\$13,712
Real-Time Supplement	\$25,596	\$6,399
BLA Efficacy Supplement	\$365,657	\$91,414
30-Day Notice	\$5,851	\$2,926
Annual Fee for Periodic Reporting on a Class III device (PMAs, PDPs, and PMRs)	\$12,798	\$3,200

† For small businesses with an approved SBD.

‡ Note: 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.

Small businesses with an approved SBD with gross receipts or sales of \$30 million or less are eligible to have the fee waived on their first PMA, PDP, PMR, or BLA.

Annual Establishment Registration Fee: \$5,546. No small business reduced fee.