Premarket Notification 510(k) Medical Device User Fees

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Center for Devices and Radiological Heath
Office of Device Evaluation

MDUFMA

Medical Device User Fee Modernization Act of 2002

User Fees for Device Reviews

www.fda.gov/oc/mdufma

MDUFMA

Types of Premarket Applications Submitted to CDRH Requiring a User Fee:

- 510(k)s
- 513(g)s
- PMAs

Step #1 in User Fee Process

- Obtain Small Business Determination (SBD)

www.fda.gov/oc/mdufma

- Guidance allows 60 days to process SBD, but is currently reviewed in 10-15 days.

- Must receive "SBD number" before going to next step

Please Note:

Businesses not qualifying as "small" can skip this step and continue on to the user fee cover sheet.

Step #2 in User Fee Process

- Create User Fees Cover Sheet
  www.fda.gov/oc/mdufma
- Payment Identification Number
- Fax to 240-276-4025 and include in your 510(k) submission.

Step #3 in User Fee Process

- Payment & 510(k) are mailed to separate addresses
- Generate check (Paper or Electronic) for appropriate amount.
- Credit Card use is encouraged for payments up to $4,000
- Mail Paper Check to US Bank (St. Louis, MO)
- Wire Transfer - If wiring the user fee, please include a $35 processing fee in addition to your payment.
  - Once the payment has been successfully processed by US Bank, and the Center has been notified, a letter will be faxed to your firm from FDA stating that your 510k is under review.

User Fee Information

- User Fee hold letter will be issued if the payment has not been received or processed.
- Always call or e-mail the user fee contact person if you believe you received this letter in error.
- If 510(k) or 513(g) has been placed under review, a letter confirming this will always be faxed to the firm. If you do not receive this letter, please contact the user fee contact person.

User Fee Information

- 510(k) and 513(g) User Fee is Per Submission.
- Establishment Registration Submitted Annually (Oct. – Dec.)
- Establishment Registration is a separate fee from the 510(k) and 513(g).

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Projected Fees, FY 2009 – FY 2012

FY09 – Standard Fee $3,693

Small Business Fee $1,847

FY10 – Standard Fee $4,007

Small Business Fee $2,004

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Projected Fees, FY 2009 – FY 2012

FY11 – Standard Fee $4,348
Small Business Fee $2,174

FY12 – Standard Fee $4,717
Small Business Fee $2,359

User Fee Contact Information

Small Business Determinations and General Questions:

DSMICA@fda.hhs.gov

User Fee Staff:

userfees@fda.gov

301-796-7200.

Establishment registration:

reglist@cdrh.fda.gov

240-276-0111

Information Highway

FDA Homepage: www.fda.gov

Device Advice:
www.fda.gov/cdrh/devadvice

Search Federal Register:
www.accessdata.fda.gov/scripts/oc/ohrms/index.cfm

Code of Federal Regulations (CFR):
www.fda.gov/cdrh/devadvice/365.html

Federal Food, Drug, and Cosmetic Act:
www.fda.gov/opacom/laws/fdcact/fdctoc.htm

Information Highway

CDRH Publicly Searchable Databases

www.fda.gov/cdrh/databases.html

This website contains over 15 publicly searchable FDA Databases.

510k Substantial Equivalence Decision-Making Process

Guidance & Flowchart

www.fda.gov/cdrh/k863.html