Form Approved: OMB No. 0910-511 Expiration Date: January 31, 2010. See Instructions for OMB Statement.

DEPARTMENT OF HEALTH AND HUMAN SERVICES FOOD AND DRUG ADMINISTRATION **MEDICAL DEVICE USER FEE COVER SHEET**	PAYMENT IDENTIFICATION NUMBER: **MDXXXXXX-956733** Write the Payment Identification number on your check.

A completed cover sheet must accompany each original application or supplement subject to fees. If payment is sent by U.S. mail or courier, please include a copy of this completed form with payment. Payment and mailing instructions can be found at: http://www.fda.gov/oc/mdufma/coversheet.html

1. COMPANY NAME AND ADDRESS (include name, street address, city state, country, and post office code)	2. CONTACT NAME
	2.1 E-MAIL ADDRESS
	2.2 TELEPHONE NUMBER (include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	2.3 FACSIMILE (FAX) NUMBER (Include Area code)

3. TYPE OF PREMARKET APPLICATION (Select one of the following in each column; if you are unsure, please refer to the application descriptions at the following web site: http://www.fda.gov/oc/mdufma

Select an application type:	3.1 Select a center
[ ] Premarket notification(510(k)); except for third party	[ ] CDRH
[ ] 513(g) Request for Information	[ ] CBER
[ ] Biologics License Application (BLA)	3.2 Select one of the types below
[ ] Premarket Approval Application (PMA)	[ ] Original Application
[ ] Modular PMA	Supplement Types:
[ ] Product Development Protocol (PDP)	[ ] Efficacy (BLA)
[ ] Premarket Report (PMR)	[ ] Panel Track (PMA, PMR, PDP)
[ ] Annual Fee for Periodic Reporting (APR)	[ ] Real-Time (PMA, PMR, PDP)
[ ] 30-Day Notice	[ ] 180-day (PMA, PMR, PDP)

4. ARE YOU A SMALL BUSINESS? (See the instructions for more information on determining this status)

[ ] YES, I meet the small business criteria and have submitted the required qualifying documents to FDA	[ ] NO, I am not a small business

4.1 If Yes, please enter your Small Business Decision Number:

5. FDA WILL NOT ACCEPT YOUR SUBMISSION IF YOUR COMPANY HAS NOT PAID AN ESTABLISHMENT REGISTRATION FEE THAT IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHMENT REGISTRATION FEES THAT ARE DUE TO FDA?

[ ] YES (All of our establishments have registered and paid the fee, or this is our first device, and we will register and pay the fee within 30 days of FDA's approval/clearance of this device.)

[ ] NO (If "NO," FDA will not accept your submission until you have paid all fees due to FDA. This submission will not be processed; see http://www.fda.gov/cdrh/mdufma for additional information)

6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE APPLICABLE EXCEPTION.

[ ] This application is the first PMA submitted by a qualified small business, including any affiliates	[ ] The sole purpose of the application is to support conditions of use for a pediatric population
[ ] This biologics application is submitted under section 351 of the Public Health Service Act for a product licensed for further manufacturing use only	[ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially

7. IS THIS A SUPPLEMENT TO A PREMARKET APPLICATION FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC POPULATION THAT NOW PROPOSES CONDITION OF USE FOR ANY ADULT POPULATION? (If so, the application is subject to the fee that applies for an original premarket approval application (PMA).

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION	

MDUFMA User Fees Cover Sheet

The Medical Device User Fee Cover Sheet is required for your Medical Device Application Submission. After completing the cover sheet, you will be assigned a unique user fee payment identification number that distinguishes and tracks your fee payment and submission.

How to Fill Out the MDUFMA User Fee Cover Sheet On-line:

FDA offers your organization the ability to complete a Medical Device User Fee Cover Sheet online and submit it electronically. To fill out the form online, you need Microsoft Internet Explorer 5.5 or higher or Netscape Navigator 4.7 or higher.

Read the instructions below and then go to Create MDUFMA User Fee Cover Sheet to fill out the form.

1. You will register on-line by providing the following information:

- One of the following: Employer Identification Number (EIN), Dun & Bradstreet Number (DUNS), or Organization Number
- Contact Name
- Company Name
- Address
- City
- State
- Zip Code
- Country
- Telephone
- Fax
- E-mail

EIN numbers are required for U.S. firms, and DUNS numbers are recommended (but optional) for foreign firms. If you have previously registered with the FDA User Fee System for an ADUFA or PDUFA cover sheet, you will have been issued an Organization ID number (Org ID). The Org ID uniquely identifies your organization to the FDA. You will need one of these three numbers to proceed with registration.

2. Fill out the Medical Device User Fee Cover Sheet. Please answer a series of questions regarding the type of application being submitted for FDA's review. You will have the opportunity to view the cover sheet in draft form before submitting it to FDA.

3. When you are done, click the SUBMIT button to complete the cover sheet submission process. A form will appear with an electronically generated user fee payment identification

number that is located in the upper right-hand corner, beginning with the letters MD. This number will assist FDA in tracking your payment and submission for the review process.

Submitting Payment

Please send a printed copy of the completed Cover sheet along with a check, bank draft, or U.S. Postal money order made payable to the Food and Drug Administration for the fee amount due. Remember to include the Payment Identification Number, beginning with 'MD', and the FDA P.O. Box on the enclosed check.

Mail payment and cover sheet to:

US Bank Lock Box
P.O. Box 956733
St. Louis, MO 63195-6733
Note: In no case should payment be submitted with the application.

If checks are to be sent by a courier that requires a street address, the courier can deliver the checks to:

US Bank
ATTN: Government Lockbox 956733
1005 Convention Plaza
St. Louis, MO 63101
Note: This address is for courier delivery only. Contact the US Bank at 314-418-4821 if you have any questions concerning courier delivery.

If using a wire transfer, you may send your payment using the following information. You are responsible to pay any administrative costs associated with the processing of a wire transfer. Contact your bank or financial institution regarding additional fees. Please note that the review of your applications can not begin until full payment is received.

US Department of Treasury
TREAS NYC
33 Liberty Street
New York, NY 10045
FDA Deposit Account Number: 75060099
US Department of Treasury routing/transit number: 021030004
SWIFT Number: FRNYUS33
Please include the user fee payment identification number, beginning with "MD" and ensure that the fee that your bank will charge for the wire transfer is added to your fee payment.

Mailing the Application

Mail application and include a *copy* of the completed Cover sheet as the first page of your application and each copy to:

U.S. Food and Drug Administration
Center for Devices and Radiological Health
Document Mail Center – WO66-G609
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

or

Food and Drug Administration
Center for Biologics Evaluation and Research
1401 Rockville Pike, Suite 200 N
HFM-99 (Document Control Room)
Rockville, MD 20852-1448

If You Have Problems:

If you already submitted an application and/or payment and forgot your user fee payment identification number or are unable to use the online system:

Contact the FDA User Fees Financial Support Team at 301-796-7200 or via email at userfees@fda.gov.

If you are unsure whether or not you need to file an application with FDA or are unsure what type of application to file

Contact: Division of Small Manufacturers, International, and Consumer Assistance (DSMICA)
FDA Center for Devices and Radiological Health
1-800-638-2041 or 301-796-7100

Contact: Office of Communication, Training and Manufacturers Assistance FDA Center for Biologic Evaluation and Research 301-827-2000

- Create MDUFMA User Fee Cover Sheet

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