FOOD AND DRUG ADMINISTRATION  MEDICAL DEVICE USER FEE COVER SHEET	PAYMENT IDENTIFICATION NUMBER: 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: https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/ucm370879.htm	
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)
4.4 FMDLOVED IDENTIFICATION NUMBER (FIN)	2.3 FACSIMILE (FAX) NUMBER (Include Area code)
1.1 EMPLOYER IDENTIFICATION NUMBER (EIN)	
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/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm345263.htm	
<u>Select an application type:</u>	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)
[] 30-Day Notice	[ ] Real-Time (PMA, PMR, PDP)
[ ] De Novo Request	[ ] 180-day (PMA, PMR, PDP)
4. ARE YOU A SMALL BUSINESS? (See the instructions for m	nore information on determining this status)
$[\ ]$ YES, I meet the small business criteria and have submitted qualifying documents to FDA	
4.1 If Yes, please enter your Small Business Decision Numb	per:
IS DUE TO FDA. HAS YOUR COMPANY PAID ALL ESTABLISHN	
[ ] YES (All of your establishments have registered and paid the fee, or this is your first device and you will register and pay the fee within 30 days after entering into an operation that requires you to register and submit device listing information.)	
[] NO (If you currently market a medical device and your establishment is required to register and submit device listing information, FDA will not accept your submission until you have paid all fees due to FDA. See	
http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/RegistrationandListing/ucm053165.htm for additional information)	
6. IS THIS PREMARKET APPLICATION COVERED BY ANY OF APPLICABLE EXCEPTION.	THE FOLLOWING USER FEE EXCEPTIONS? IF SO, CHECK THE
[] This application is the first PMA submitted by a qualified business, including any affiliates	small [ ] The sole purpose of the application is to support conditions of use for a pediatric population
[] This biologics application is submitted under section 351 Public Health Service Act for a product licensed for further manufacturing use only	of the [ ] The application is submitted by a state or federal government entity for a device that is not to be distributed commercially
	FOR WHICH FEES WERE WAIVED DUE TO SOLE USE IN A PEDIATRIC DR ANY ADULT POPULATION? (If so, the application is subject to the n (PMA).
PAPERWORK REDUCTION ACT STATEMENT Public reporting burden for this collection of information is estimated to average 18 minutes per response, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Send comments regarding this burden estimate or any other aspect of this collection of information, including suggestions for reducing this burden, to the address below.	

Department of Health and Human Services Food and Drug Administration Office of Chief Information Officer Paperwork Reduction Act (PRA) Staff PRAStaff@fda.hhs.gov

[Please do NOT return this form to the above address, except as it pertains to comments on the burden estimate.]

8. USER FEE PAYMENT AMOUNT SUBMITTED FOR THIS PREMARKET APPLICATION

01-May-2024

Form FDA 3601 (07/22)

"Close Window" Print Cover sheet