

Department of Health and Human Services Food and Drug Administration Center for Devices and Radiological Health	<h2 style="margin: 0;">PREMARKET NOTIFICATION [510(K)] STATUS REQUEST AND RESPONSE</h2>
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**Single Form** – To be used for *both* your request and FDA’s response. Requesters should fill in the information on the top half of this form (Request Section) and fax (or mail) this form to the FDA at the fax # or address listed below. The FDA will complete the information on the bottom half (Response Section) and return by fax (or mail).

**REQUEST SECTION** *(To be completed by requester)*

<b>To (From)</b> FDA, Center for Devices & Radiological Health Division of Small Manufacturers, International and Consumer Assistance (DSMICA) Attn: 510(k) Status Coordinator 10903 New Hampshire Avenue WO66-4613 Silver Spring, MD 20993 USA  Fax Number: (301) 847-8149 Phone: (301) 796-7100 or (800) 638-2041	<b>From (To)</b> <table border="1" style="width: 100%; border-collapse: collapse;"> <tr><td style="padding: 2px;">REQUESTER NAME</td></tr> <tr><td style="padding: 2px;">MAILING ADDRESS</td></tr> <tr><td style="padding: 2px;">FAX NUMBER</td></tr> <tr><td style="padding: 2px;">TELEPHONE NUMBER</td></tr> <tr><td style="padding: 2px;">REQUESTER’S AFFILIATION WITH THE SUBMITTER OF THE 510(K)</td></tr> </table>	REQUESTER NAME	MAILING ADDRESS	FAX NUMBER	TELEPHONE NUMBER	REQUESTER’S AFFILIATION WITH THE SUBMITTER OF THE 510(K)
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REQUESTER’S AFFILIATION WITH THE SUBMITTER OF THE 510(K)						

**Requester Certification:** I certify that I am an authorized representative of the submitter of the following 510(k) and that all information provided herein is truthful to the best of my knowledge. Please provide me with information related to the status of the following 510(k) submission via *(mark one)*: FAX  or MAIL

510(K) NUMBER	REQUESTER SIGNATURE
SPONSOR’S NAME AND ADDRESS	PRODUCT NAME
	DATE LOGGED IN BY FDA (ODE) – <i>as identified in acknowledgement letter</i>

**RESPONSE SECTION** *(To be completed by FDA)*

**NOTE: THIS DOCUMENT IS INTENDED ONLY FOR THE USE OF THE PARTY TO WHOM IT IS ADDRESSED AND CONTAINS INFORMATION THAT IS PRIVILEGED, CONFIDENTIAL, AND PROTECTED FROM DISCLOSURE UNDER APPLICABLE LAW.**

If you are not the addressee, or authorized to deliver this document to the addressee, you are hereby notified that review, disclosure, dissemination, copying, or other action based on the content of this communication is not authorized. If document has been received in error, please notify FDA by phone and return via mail.

**Reviewing Branch:** \_\_\_\_\_ .

Please be advised that the average total time (time for FDA review plus time spent awaiting any additional data) for review of a device assigned to this branch has been \_\_\_\_\_ days over the last 6 months.

	LAST ACTION AND DATE
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**Place in Queue:** Your 510(k) has been assigned to a reviewer and is # \_\_\_\_\_ in line for that reviewer to work on. The length of time that it will take for the reviewer to get to your 510(k) and to review it will depend on many factors, such as the complexity of the 510(k)’s that are in line ahead of you, and other work assigned to the reviewer, for example the review of investigational device exemption submissions. Because of these variables, we cannot estimate a completion date for review of your 510(k). However, future inquiries can give you an idea of how your 510(k) is progressing.

	FDA RESPONSE DATE
<i>Please do not request another status report prior to 30 days from the FDA response date.</i>	

Public reporting burden for this collection of information is estimated to average 0.2 hour 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:

Department of Health and Human Services  
Food and Drug Administration  
Office of Chief Information Officer  
1350 Piccard Drive, Room 400  
Rockville, MD 20850