PREMARKET NOTIFICATION [510(K)] STATUS REQUEST & RESPONSE

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*)** **********

To (From)
510(k) Status Coordinator
Div. of Small Manufacturers Assist.
FDA, Center for Devices &
Radiological Health
5600 Fishers Lane (HFZ-220)
Rockville, MD 20857 USA
Fax Number: (301)443-8818
Phone: (301)443-6597 / (800)638-2041

From (To)
Requester Name: _____
Mailing Address: _____
_____
_____
FAX Number: _____
Telephone Number: _____
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 : FAX [ ] or MAIL [ ]

510(K) Number: K_____ Requester Signature: _____
Sponsor's Name and Address: _____
Product Name: _____

Date logged in by FDA (ODE) as identified in acknowledgement letter: _____

========== **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:_____

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. Due to 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: _____ Please do not request another status report prior to 30 days from the FDA response date.