

## Premarket Notification (0910-0120)

### Change Request (83C)

**March 24, 2016**

FDA is submitting this change request to reflect the availability of a web interface for accepting premarket notification (510(k)) submissions under this ICR. Currently, all respondents to this ICR are required to submit an electronic copy (CD or thumb drive) along with the paper copies required by regulation (see ICR approved through January 31, 2017). In order to further streamline and modernize the electronic submission process for respondents and FDA reviewers, we are testing a 510(k) template using FDA's existing eSubmitter system, which is currently in use for a variety of other FDA submission programs in multiple other Centers. We expect to test the system for approximately six months.

Participation in testing is voluntary. We expect that approximately 30-100 respondents will participate. These volunteers come from the approximately 3,900 respondents in the existing respondent pool for this ICR. The eSubmitter system is used for many other FDA programs and it is our expectation that volunteers will be familiar with the eSubmitter system. During the testing, participants will construct their 510(k) via the eSubmitter system instead of producing a paper/eCopy submission. The system uses prompts to walk applicants through the submission process. All data fields in the 510(k) eSubmitter module reflect information already required in the regulations and recommended in supplementary guidance documents (screen captures of the test module are attached). All of the information is included in the currently approved burden estimate for the 510(k) program. For these reasons, we do not anticipate a change in estimated burden. However, we intend to re-evaluate this upon completion of the testing and, upon public notice and comment, submit a request for revision for any resulting changes to the burden estimate.

In 2014, we conducted a small pilot (5 participants) intended to test the eSubmitter template. We tested the questions, usability, layout, and design of the template. We requested feedback via email address [eSubpilot@fda.hhs.gov](mailto:eSubpilot@fda.hhs.gov) and via a Federal Register notice (May 1, 2014, 79 FR 24732). We received all of our feedback (mostly positive) via the email address. Based on our experience with the 2014 pilot, we will be passively collecting feedback via the same email address, which is included in the template as well as the "MyDevices" webpage. We will handle feedback for the second pilot the same way as the first pilot. Emailed suggestions are tracked in a spreadsheet (we will be adding to the same spreadsheet we used for the first pilot). During and after the pilot, we will evaluate each suggestion and provide to the submitter feedback including how/whether we made changes based on the suggestion.

However, the focus of the current testing is on functionality in two areas: (1) The "MyDevices" webpage, which serves as a portal for submission of the premarket notification package produced by the eSubmitter template. The MyDevices webpage allows the applicant to track the status of the submission as it is reviewed and provides a centralized help station for asking questions, which are automatically routed to the correct group. Specifically, we intend to test the functionality of the status and routing systems. As noted above, we will provide an email address to which participants may send suggestions or notify us if there is an issue with the status or help routing systems. (2) We will also test the functionality of the interface for FDA reviewers.