

2011 (approved by OMB on 3/21/2011)	2013 Version	Type of Change	Reason for Change	Burden Change
Section E. Substantial Clinical Improvement information:				
Second Sentence ...This discussion must include evidence (typically, but not necessarily, in the form of published peer-reviewed clinical trials) to demonstrate that the device under consideration satisfies one or more of the measures of "substantial clinical improvement" that are listed above in this announcement.	Second Sentence ...This discussion must include evidence to demonstrate that the device under consideration satisfies one or more of the measures of "substantial clinical improvement" that are listed above in this announcement.	Rev	Parenthetical language has been removed, and replaced with clearer language (below)	No
n/a	Last Sentence ...While we prefer published peer-reviewed clinical trials, we accept all supporting evidence.	Add	Sentence has been added, to more clearly state than non-published clinical research is also acceptable, although not preferred.	No

Type of Change: Rev = Revision, Del = Deletion, Add = Addition, and Red = Redesignation.