



ASCA eSTAR Form

For devices that are part of the ASCA program

Introduction

This template is intended for use in both constructing the biocompatibility section for a medical device premarket application/submission that contains testing from an ASCA-accredited test lab, and in being a resource of medical device premarket regulations. This template is only used for constructing the biocompatibility section that contains testing from an ASCA-accredited test lab, not the entire application or submission. Once complete, this section should be included with the rest of your application or submission.

Key

A **Red Bar** indicates the associated required question, or a required question in that section, wasn't answered.

A **Green Bar** indicates the associated required question, or all required questions in that section, was answered.

A **Grey Bar** indicates the associated question is optional. Green and Grey Bars act as left borders when present.

? Blue Help Text Buttons when clicked display regulatory information pertaining to the question or section heading they immediately follow. Assistive Technology (AT) users including text to speech, will hear "Help Text Button." If activated, the help text windows will open, and can be closed by tabbing to the OK key and pressing return.

[Hover Text] Hover text displays information about your application, such as the date an attachment was attached, or, if the section corresponds to an [IMDRF](#) harmonized section, the hover text will display the chapter number of the [IMDRF Table of Contents](#).

Form Approved: OMB Control No. 0910-0889
OMB Expiration Date: XX/XX/20XX

PRA Statement

This section applies only to requirements of the Paperwork Reduction Act of 1995.

DO NOT SEND YOUR COMPLETED FORM TO THE PRA STAFF EMAIL ADDRESS BELOW.

The burden time for this collection of information is estimated to average 1 hour per response, including the time to review instructions, search existing data sources, gather and maintain the data needed and complete and review the collection of information. Send comments regarding this burden estimate or any other aspect of this information collection, including suggestions for reducing this burden, to:

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

"An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB number."

Biocompatibility

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If this section is not applicable, please attach a statement explaining why.

Tissue Contacting Products/Components/Materials

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How many tissue contacting products/components/materials are there?

(See Help Text if multiple materials share the same justification for no testing.)

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Biocompatibility Reports and Documentation

Add Attachment

Please attach any documentation (e.g., test reports) pertaining to the biocompatibility of your device. If no test reports were attached, please attach a rationale explaining why testing is not necessary.