**软件描述**

**(Software Description)**

项目编号（Project No.）:

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版本（Version）:

编制（Author）：

审核（Audit）：

批准（Approve）：

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****{文档背景说明：****

**provide a comprehensive overview of the device features that are**

**controlled by software, and describe the intended operational environment. Generally, we recommend that you provide the information in paragraph format and highlight major or operationally significant software features. The software description should include information on the following:**

**· programming language**

**· hardware platform**

**· operating system (if applicable)**

**· use of Off-the-Shelf software (if applicable).**

**If your device uses Off-the Shelf software, please refer to the FDA guidance document“Guidance for Off-the-Shelf Software Use in Medical Devices.”**

**If this information is included in another document, such as the Software Requirements Specification, your submission should contain an annotation and a reference to the document in the submission where this information is located.}**

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