**（确认和验证文档）**

**Verification and Validation Documentation**

项目编号（Project No.）:

文件编号（Document No.）:

文件类型（Document type）：

版本（Version）:

编制（Author）：

审核（Audit）：

批准（Approve）：

**Table of Contents**

[1. 测试总结（Summary of test） 4](#_Toc5772)

[2. 测试程序概述(Test Procedure Overview) 4](#_Toc10862)

[2.1 测试任务(Test Task) 4](#_Toc22839)

[3. 测试方法/内容/结果(Test Methods, Contents and Results) 4](#_Toc4865)

[3.1 软件确认/验证过程描述（Description of software verification/validation processes） 4](#_Toc16365)

[3.2测试方法(Test Methods) 4](#_Toc30921)

[3.3 测试内容和结果(Test Contents and Results) 4](#_Toc4171)

# {文档背景说明：

The terms “verification” and “validation” described earlier in this document refer to two phases of Software Device testing. This section recommends the type of testing documentation you should include in a premarket submission for a Software Device, based on the Level of Concern.

**Minor Level of Concern Devices**

For Minor Level of Concern devices, we recommend that you submit documentation of

system or device level testing, and, where appropriate, integration testing. The

documentation submitted should include system or device level test pass/fail criteria and a summary of the test results.

**Moderate Level of Concern Devices**

For Moderate Level of Concern devices, we recommend that you submit a summary list of validation and verification activities and the results of these activities. We also recommend that you submit your pass/fail criteria. You should ensure that the Traceability Analysis effectively links these activities and results to your design requirements and specifications

**Major Level of Concern Devices**

For Major Level of Concern devices, we recommend that you submit the information

recommended above for Moderate Level of Concern devices and a description of any tests that were not passed. We also recommend that you include any modifications made in response to failed tests and documentation of results demonstrating that the modifications were effective. Documentation provided in your submission should include examples of unit integration testing and a summary of the results.}

# *一、阶段测试*

# *1.* *测试总结（Summary of test）*

# *2. 测试程序概述(Test Procedure Overview)*

## *2.1 测试任务(Test Task)*

***2.2.1 任务描述(Task description)***

***2.1.2 测试范围 (Test range)***

# ***3. 测试方法/内容/结果(Test Methods, Contents and Results)***

## ***3.1 软件确认/验证过程描述（Description of software verification/validation processes）***

## ***3.2测试方法(Test Methods)***

## ***3.3 测试内容和结果(Test Contents and Results)***

*备注：具体可包括测试项目、测试方法、可接受准则、测试结果等*

# *二、系统测试*