Recommended Content and Format of Complete Test Reports for Non-Clinical Bench Performance Testing in Premarket Submissions

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Draft Guidance for Industry and Food and Drug Administration Staff

DRAFT GUIDANCE

This draft guidance document is being distributed for comment purposes only.

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For questions about this document, contact the ODE Regulatory Advisors at CDRH-ODERegAdvisors@fda.hhs.gov.

U.S. Department of Health and Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Preface

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This draft guidance, when finalized, will represent the current thinking of the Food and Drug Administration (FDA or Agency) on this topic. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations. To discuss an alternative approach, contact the FDA staff or Office responsible for this guidance as listed on the title page.

I. Introduction and Scope

The Food and Drug Administration (FDA) has developed this document to describe relevant information that should be included in complete test reports for non-clinical bench performance testing provided in a premarket submission (i.e., premarket approval (PMA) applications, humanitarian device exemption (HDE) applications, premarket notification (510(k)) submissions, investigational device exemption (IDE) applications and De Novo requests).

For the purpose of this document, non-clinical bench performance testing is defined as performance testing that encompasses all bench testing and will be dependent upon the specifics of the actual device or device type. Non-clinical bench performance testing includes, but is not limited to: mechanical and biological engineering performance (such as fatigue, wear, tensile strength, compression, burst pressure); bench tests using animal or human tissue; and animal carcass or human cadaveric testing.

Non-clinical bench performance testing excludes biocompatibility evaluation, sterilization, and animal *in vivo* evaluation. Test reports for clinical studies, animal studies, and studies evaluating the performance characteristics of *in vitro* diagnostic devices are excluded from the scope of this document.

The information listed below is intended to help ensure that clear and consistent information is provided in premarket submissions containing non-clinical bench performance testing.[1] The information in this guidance is intended to be used in conjunction with other FDA guidance documents, including device-specific guidances.

FDA's guidance documents, including this guidance, do not establish legally enforceable responsibilities. Instead, guidances describe the Agency's current thinking on a topic and should be viewed only as recommendations, unless specific regulatory or statutory requirements are cited. The use of the word *should* in Agency guidance means that something is suggested or recommended, but not required.

II. Test Report Information

Complete test reports for non-clinical bench performance testing should include the objective of the test, description of test methods and procedures, pre-defined pass/fail criteria, test results, and discussion of conclusions. To facilitate FDA's review, we recommend that all premarket submissions containing complete test reports for non-clinical bench performance testing also include a summary report that summarizes the conducted testing.

Complete test reports are not needed for Special 510(k)s or for tests for which a Declaration of Conformity to an appropriate FDA-recognized consensus standard is provided. For additional information regarding the use of consensus standards and a Declaration of Conformity, refer to the guidance on "Recognition and Use of Consensus Standards." [2]

A. Summary Reports

We recommend that in the body of your submission you briefly describe all testing performed in a tabulated summary that includes the following:

1. Test performed
2. Objective of the test
3. Brief description of the test methods/procedures, including sample size, device(s) tested, and any standard(s) utilized

[1] The recommendations in this guidance are consistent with the least burdensome provisions (see Sections 513(c), 513(i), 515(c), 515(i) of the Federal Food, Drug, and Cosmetic Act) and guiding principles described in the draft guidance "The Least Burdensome Provisions: Concept and Principles" (https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM588914.pdf), which when finalized, will represent FDA's current thinking.

[2] https://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm077295.pdf

4. Pre-defined pass/fail criteria, including the clinical/scientific justification for the chosen criteria

5. Results summary
    a. For quantitative assessments, specify the mean, maximum, minimum, and standard deviation.
    b. Specify whether the acceptance criteria were met or not.
    c. Provide a brief explanation of any test failures and/or deviations.

6. Discussion of the conclusions
    a. Discuss the clinical significance of the conclusions.
    b. For 510(k) submissions, include an explanation of how the data generated supports a finding of substantial equivalence (e.g., comparison to predicate device testing, dimensional analysis).

7. Location (e.g., appendix and page number) in the submission for each test report

B. Test Reports

Complete test reports should include the following:

1. Test performed

You should clearly state the test that was conducted.

2. Objective of the test

You should state the purpose of the test that was conducted.

3. Description of test methods and procedures

We recommend that you include the following items in the description of test methods and procedures:

a. Test Sample Information

You should provide a description of the sample that is tested, whether that is the device itself or a part or attribute of the device (e.g., the device's material composition/properties or packaging). The tested devices should represent the final, finished device that has been subjected to all manufacturing processes (including sterilization), environmental conditioning and simulated transportation. If you conducted any testing on samples that are not the final, finished (e.g., sterilized) product or subassemblies, we recommend that you indicate this in the test protocol and test summary table, and provide a justification explaining why this approach is appropriate. Also, we recommend that you specify the number of

sterilization cycles and other conditioning (e.g., simulated use, environmental conditioning, distribution simulation) the samples have been exposed to prior to testing. If test samples were conditioned or sterilized in a manner that is different than what is intended for the marketed product, we recommend that you provide a justification for this being worst-case for all attributes being tested.

b. Test Sample Size/Selection

We recommend providing a scientific rationale to support the number of samples tested. For 510(k) submissions, the sample size should provide reasonable assurance that the test results support the substantial equivalence of the device. The sample size selected should be supported by your risk assessment and sampling plan. Additionally, if one device model is used to represent all device models included in your submission, you should justify why the tested device is representative of the entire product matrix or explain why the tested device represents the worst-case design for that respective test. Finally, your test sample selection should consider both inter- and intra-lot variability by examining multiple manufacturing lots, when appropriate.

c. Test Protocol

The test protocol should contain enough detail that an individual familiar with testing of the device type will be able to interpret the purpose of the test, how the test was conducted, and whether the test setup is appropriate to assess the performance of the device type. The test protocol should include the test parameters, including an explanation of and rationale for critical test parameters. The test protocol should also include acceptance criteria with scientific or clinical justification for the relevancy of the acceptance criteria to the intended use of the device, test sample information, and test methodology.

If FDA-recognized consensus standards that include test methods are utilized during testing, providing the test protocol is unnecessary, even when a Declaration of Conformity to the standard is not provided. Instead, you should provide a full citation of the standard, including the version, and information regarding the extent to which the standard was followed, including deviations from the standard. When the FDA-recognized consensus standard includes choices related to, for example, what is to be tested, which test methods to use, or performance limits to assess conformity, you should include an explanation for the choices and selections made.

4. Pre-Defined Pass/Fail Criteria

You should report the acceptance criteria that you use, including specifications or acceptance and rejection criteria, and a clinical/scientific justification for the specification or acceptance and rejection criteria based on the clinical requirements of the device.

5. Test Results

We recommend that you include the following items in your test results:

a. Data Points

We recommend that you include all data points collected for the tests conducted to support the premarket submission, where appropriate. This data should be accompanied by a summary of the data (e.g., minimum, maximum, average and standard deviation). You should consider using consistent units throughout your testing. If the data reported is rounded, you should specify to which significant digit.

b. Data Analysis

You should analyze the data, including any outlying points and anomalous results, and explain whether the data meet acceptance criteria. We recommend that you conduct data analyses for your test results using statistical analyses when appropriate, and specify whether the acceptance criteria were met. If the data analysis concludes that the acceptance criteria were not met for either individual samples or entire sample populations, we recommend that you discuss the potential reasons for test failure, determine if re-testing is appropriate, risk mitigation measure(s), and provide justification for why the results are considered acceptable and support a favorable decision on your premarket submission.

c. Protocol Deviations

We recommend that you describe any protocol deviations, the activities executed to determine the source of the deviation, and the impact on the test results and conclusions you have drawn from the test.

6. Discussion of the conclusions

We recommend that you describe the conclusions drawn from the test results and the clinical significance of the conclusions.

For 510(k) submissions, you should discuss how the conclusions demonstrate substantial equivalence of your device to the identified primary predicate device based on known clinical performance, device performance specifications publicly available, and/or relevance of your specified acceptance criteria to the intended use of the device.