# ODE Review Memorandum for Traditional and Abbreviated 510(k) Submissions

## Preparing a Review Memorandum

When your review is complete, you should prepare a review memorandum. The review memorandum summarizes the information in the submission and documents your evaluation. The level of documentation for a review memorandum may vary, depending on the complexity of the device, its intended use, and any questions raised in the review.

## Content of a Review Memorandum

ODE typically includes the information described below. The review memorandum should cover the key points succinctly and include your analysis of how the information demonstrates substantial equivalence.

### Submission Information

You should provide identifying information such as the 510(k) number, submitter, and trade name of the device.

### Administrative Information

All 510(k) submissions must include a Truthful and Accuracy Certification, and either a 510(k) Summary or 510(k) Statement.[1] Submissions also include an Indications for Use Statement and, when appropriate, other administrative documents e.g., a kit certification.[2] You should verify these were provided and indicate the page numbers for each.

### Reason for the Submission

You should identify the type of submission, Abbreviated or Traditional, and the reason for the submission (i.e., whether it is for the first time introduction of the device to the US market or for a modification of the submitter's legally marketed device). If it is for a modification, you should describe the nature of the modification, e.g., change in design, material, chemical composition, energy source, manufacturing process, labeling, and intended use.

### Device Classification

You should identify the Code of Federal Regulations (CFR) section and three-letter product code for the device and any accessories included in the submission. This

[1] For information see Truthful and Accuracy Certification, 21 CFR 807.87(k); 510(k) Summary, 21 CFR 807.92; 510(k) Statement, 21 CFR 807.93.

[2] http://www.fda.gov/cdrh/ode/odecl874.html.

information should be supplied by the submitter and is available in FDA's Classification Database.[3] Occasionally, the classification or product code you identify may differ from that proposed by the submitter. You should explain any discrepancies.

## Intended Use

You should identify the indications for use as described on the submitter's Indications for Use Statement.[4] Indicate whether the device is intended for prescription use (professional use) and/or over-the-counter (OTC) use. You should ensure the Indications for Use Statement is consistent with the proposed labeling and whether the submission contains labeling sufficient to describe the device, its intended use, and the directions for its use as required by 21 CFR 807.87(e). The directions for use should be sufficiently detailed to enable the user to achieve the desired result.

## Device Description

You should describe the major features, such as design, materials, and mechanism of action. You should indicate how the device will be supplied to the end-user, e.g., sterile. You should identify all accessories included in the submission and whether any accessories or components will be marketed separately.

## Performance Characteristics

You should briefly describe the methods or tests used to characterize the performance of the device relative to legally marketed devices. You should include a summary of the results and the acceptance criteria . You should identify any standards or guidance that were referenced and note any use of declarations or statements of conformity.

## Comparison to Legally Marketed Devices

You should identify the legally marketed or "predicate"[5] device(s), including 510(k) submission numbers, to which the submitter's device is being compared. In this section, you should summarize how the submitter's device is similar to and different from legally marketed devices.

## Deficiencies and Resolution

If you identified any deficiencies during your review, you should summarize them and discuss how they were resolved. You should identify any additions the submitter made, whether on their own initiative or at your request. (See also the guidance, **Suggested Format for Developing and Responding to Deficiencies in Accordance**

[3] http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm
[4] http://www.fda.gov/cdrh/ode/indicate.html and http://www.fda.gov/cdrh/ode/INDICUSE.HTML.
[5] http://www.fda.gov/cdrh/devadvice/31432.html

**with the Least Burdensome Provisions of FDAMA**[6] for assistance developing direct, concise, and complete deficiencies when requesting additional information.)

## Reviewer's Analysis

You should provide your analysis of whether the submitter's information demonstrates substantial equivalence. Your analysis should highlight how you considered the issues relevant to substantial equivalence raised by the intended use, technological characteristics, and performance of the device. This may include whether the submitter has:

- fully described the device
- been consistent in describing the device and its intended use throughout the submission
- adequately compared the device to legally marketed devices
- identified the potentially significant differences
- conducted appropriate testing
- provided sufficient information on test methods
- provided test results sufficient to assess the differences
- addressed issues raised in relevant FDA guidance
- applied standards appropriately

## Reviewer's Recommendation

You should, based on your analysis, state your recommendation, i.e., whether FDA should determine the device is substantially equivalent or not substantially equivalent.

## Reviewer's Signature

Type your name under the signature line and sign and date the memo.

[6] http://www.fda.gov/cdrh/modact/guidance/1195.html