SOPP 8770: Deciding When to Submit a 510(k) for a Change to an Existing Device

Version #1

Effective Date: January 13, 2005

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1. **Purpose**

The purpose of this document is to describe the procedures for CBER staff to follow when reviewing whether a 510(k) should be submitted relating to a device change.

2. **Background**

The Center for Devices and Radiologic Health (CDRH) standardizes the review of Investigational Device Exemptions (IDE), Premarket Notification (510(k)), and Premarket Approval (PMA). premarket notifications by issuing review procedures for staff to follow. The Center for Biologics Evaluation and Research (CBER) also reviews and clears premarket notifications under the same authority, FD&C Act.

In an effort to harmonize review principles and procedures between centers, CBER has decided to adopt existing CDRH procedures, also known as Blue Book Memoranda, when feasible. When CBER cannot directly adopt existing CDRH procedures, e.g., because of issues related to a specific CBER regulated device, CBER will prepare an SOPP based on CDRH review principles with adjustments for CBER-regulated devices. In either case, CBER will issue an SOPP for staff to follow.

3. **Policy**

CBER staff will conduct their review of whether or not a 510(k) is necessary for a change based on CDRH Blue Book Memorandum: Deciding When to Submit a 510(k) for a Change to an Existing Device issued on January 10, 1997 (K97-1), with changes limited to CBER-specific administrative procedures.

4. **Responsibilities and Procedures**

CBER staff will incorporate review procedures contained in the CDRH Blue Book Memorandum: Deciding When to Submit a 510(k) for a Change to an Existing Device issued on: January 10, 1997, when reviewing applicable 510(k) issues.

The attached Blue Book Memoranda (BBM) version has been approved for CBER review purposes by Center management. Revisions to this BBM will need CBER management approval prior to implementation. Thus, reviewers should access this BBM only through this SOPP to ensure CBER review process integrity is maintained.

5. **Appendix**

Deciding When to Submit a 510(k) for a Change to an Existing Device, January 10, 1997

6. **Effective Date**
   January 13, 2005

7. **History**

Written/Revised	Approved	Approval Date	Version Number	Comment
Len Wilson	Robert A. Yetter, PhD	October 13, 2005	1	Original version written by RMCC Device Review Subcommittee