SOPP 8748: Continued Access to Investigational Devices During PMA Preparation and Review

Version #1

Effective Date: January 11, 2005

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1. Purpose

The purpose of this document is to describe the procedures for CBER staff to follow when considering continued access to investigational devices during the preparation and review of a Premarket Approval application (PMA)

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 evaluate a request for continued access to an investigational device while the PMA is being developed and reviewed based on CDRH Blue Book Memorandum: Continued Access to Investigational Devices During PMA Preparation and Review, issued on July 15, 1996 (D96-1), 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: Continued Access to Investigational Devices During PMA Preparation and Review, July 15, 1996 (D96-1), when reviewing applicable PMAs.

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

Continued Access to Investigational Devices During PMA Preparation and Review, July 15, 1996 (D96-1)

6. Effective Date

January 11, 2005

7. History

Comment / Revision	Approved By	Approval Date	Version Number	Comment
Len Wilson	Robert A. Yetter, PhD	1/11/2005	1	Original version Written by RMCC Device Review Subcommittee