510(k) Quality Review Program (Blue Book Memo I96-1) (Text Only)

This guidance was written prior to the February 27, 1997 implementation of FDA's Good Guidance Practices, GGP's. It does not create or confer rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both. This guidance will be updated in the next revision to include the standard elements of GGP's.

Integrity Memorandum - #I96-1

Office of Device Evaluation (HFZ-400)
510(k) Quality Review Program
ODE Review Staff
Through: ODE Branch Chiefs

Purpose

This memorandum modifies the independent quality review system established by Blue Book Memorandum I90-4 to enhance management and scientific oversight of the premarket notification (510(k)) review process and to further ensure the integrity and fairness of the process and the scientific propriety of the 510(k) decisions that are made. This memorandum also rescinds and replaces memo I90-4.

Background

The Department of Health and Human Services (DHHS) Office of Inspector General (OIG) in its report entitled, "Internal Control Weaknesses in the Food and Drug Administration's Medical Device 510(k) Review Process (A-15-89-00065)," recommended "(e)stablishing a quality control review system that involves an independent review of completed premarket notification decisions by an FDA group either inside or outside of ODE." The Office of Device Evaluation concurred with this recommendation, but pointed out that some mechanisms already exist to ensure quality reviews, such as involvement of immediate supervisors in the review process for all 510(k)s and further involvement of the Office of the Director, ODE, in the review of select categories of final 510(k) decisions. See Blue Book Memorandum #K94-2, "510(k) Sign-off Procedures."

Procedures

To implement this quality review system, the Office of Device Evaluation will use the following procedures to review, on a quarterly basis, a sampling of final 510(k) decisions.

1. Selection of Documents for Review - The Chief, Premarket Notification Section, will randomly select completed 510(k)s from the previous review quarter that have been found to be Substantially Equivalent (SE) or Not Substantially Equivalent (NSE) for a quality review as set forth below. The selection of 510(k)s will include devices from class I, II and III and, if available, will be selected from each classification panel designation, presently 18 in number. At least nine 510(k)s will be selected for each quarter, representing up to two 510(k)s from each panel designation per year.

2. 510(k) Quality Review Panel - A 510(k) Quality Review Panel (QRP) will be established to provide an impartial oversight function of the 510(k) review process. The QRP will be comprised of all ODE Branch Chiefs and representatives of other Center offices, as appropriate. Each 510(k) being reviewed will be assigned to a Quality Review Team, a subgroup of the QRP, for initial screening. The QRP will meet once each quarter to review the quality of the screened 510(k)s. The QRP will be chaired by the Chief, Premarket Notification Section.

3. 510(k) Quality Review Team - The 510(k) Quality Review Team (QRT) will be comprised of three members of the QRP but will not include the Chief of the Branch that completed the review and made the SE or NSE determination on the 510(k) being screened. The QRT will conduct an initial evaluation of the 510(k) assigned to it using the "510(k) Quality Review Checklist" as set forth in Attachment A. Upon completion of the checklist, the 510(k) and the completed checklist will be presented to the QRP for discussion. The Chief of the Branch that reviewed the 510(k) and issued an SE or NSE decision should be prepared to answer questions, discuss the background, and provide insight on the 510(k).

4. Document Review Procedure - The QRP will review each screened file and the accompanying checklist and reach a consensus on the following principles, which are embodied in the checklist: a. the correctness and consistency of the decision; b. the submission of the information and data necessary for the decision; c. the appropriateness and consistency of additional data requests (i.e., requests for necessary and sufficient information); d. the adequacy of documentation in the administrative record for the decision; e. the scientific correctness and the quality of the review and ultimate decision; and, f. any other analysis or comments deemed relevant and material by the QRP.

5. Summary of Findings - A summary of findings will be prepared for each 510(k) reviewed at the conclusion of the QRP quarterly review meeting. The summary of findings will include a copy of the completed checklist. The specific findings with appropriate recommendations will be distributed to the ODE Integrity Officer, the Director, ODE, and, when appropriate, to ODE Division Directors, for

follow-up actions, including corrective action, as necessary. Effective Date The QRP will be established and begin its review function during the quarter beginning June 1, 1996. Susan Alpert, Ph.D., M.D.

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Attachment A - Page 1

510(k) Quality Review Program

Section 1 -- Background Information

510(k) Number _____
Date of Final Decision _____
Final Decision _____
Product Code _____
Panel Code _____
Device Name _____
Class _____
Tier _____
Division _____
Branch _____
Submitter _____

Section 2 -- Administrative Completeness

Was the Memorandum of Record Complete: Yes No

If "NO" Why Not? _____

Section 3 -- Decision (Answer only those questions that were relevant to this 510(k))

Was the basis for the basis for the decision on each item adequate for the review/decision? (ANY NO ANSWER NEEDS AN EXPLANATION ATTACHED)

1. Same indication statement: YES NO

2. Do the difference alter the effect or raise new issues of safety or effectiveness: YES NO

3. Same technological characteristics: YES NO

4. Could the new characteristics affect the safety or effectiveness: YES NO

5. Descriptive characteristics precise enough to ensure equivalence: YES NO

6. New types of safety or effectiveness questions: YES NO

7. Accepted scientific methods exist: YES NO

8. Performance data available: YES NO

9. Data demonstrate equivalence: YES NO

Section 4 -- Summary of Findings (To be filled out at the Quality Review Panel Meeting)

Quality Review Team: _____

Was there an adequate basis for the overall scientific decision? YES NO If "NO" why not? (See Blue Book Memo K86-3)

Section 5 -- Follow-up

Issues Requiring Follow-up (please list):

Disposition of Issues:

Reviewed by: _____

More in Guidance Documents (Medical Devices and Radiation-Emitting Products) (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm)

Cross-Center Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm081752.htm)

Office of Compliance Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070269.htm)

Office of the Center Director Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm110228.htm)

Office of Communication and Education Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070271.htm)

Office of Device Evaluation Final Guidance 2010 - 2016 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm198577.htm)

Office of Device Evaluation Final Guidance 1998 - 2009 (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070272.htm)

Office of Device Evaluation Final Guidance 1976 - 1997

(/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080283.htm)

Office of In Vitro Diagnostics and Radiological Health Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070274.htm)

Office of Surveillance and Biometrics Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070275.htm)

Office of Science and Engineering Laboratories Final Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm070277.htm)

Draft Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm407274.htm)

Radiation-Emitting Products Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm283507.htm)

Withdrawn Guidance (/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm425025.htm)