510(k) Sign-Off Procedures #K94-2 (blue book memo) (Text Only)

510(k) Memorandum #K94-2

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.

June 1, 1994

Acting Director
ODE, HFZ-400

510(k) Sign-Off Procedures

ODE Review Staff
Through: ODE Branch Chiefs

Purpose

This memorandum establishes new ODE sign-off procedures for 510(k) final decision letters and requests for additional information. It rescinds and replaces Blue Book Memorandum "510(k) Memorandum #86-2 (Revised)".

Procedures

Attachment 1 is a summary of the 510(k) sign-off procedures. The three attachments to this memorandum will be updated and distributed periodically, as necessary.

1. Unable to Determine Substantial Equivalence Due to Deficiencies

   When additional information is necessary to complete a 510(k) review and the reviewer can reasonably expect the information to be submitted in 30 days from the requested date, the request for additional information letter will be signed by the Branch Chief, Associate Director or Division Director. These signed letters should be forwarded to the 510(k) DMC for dating and issuance. If the additional information requested is extensive, and cannot reasonably be expected in 30 days, the Division Director will sign the "major deficiencies/your 510(k) is withdrawn" letter. These signed letters should be forwarded to 510(k) DMC for dating and issuance. For detailed information about 510(k) additional information procedures and what letter to use refer to Blue Book Memorandum "510(k) Memorandum #K93-1.

2. Devices Exempt by Regulation from Premarket Notification

Responses to premarket notifications received for devices that are exempt by final regulation from premarket notification should be approved by and bear the signature block of the Division Director. Signed letters should then be forwarded to the 510(k) DMC for dating and issuance.

3. "Standard" Substantial Equivalency (SE) Responses

Responses to premarket notifications for devices that are substantially equivalent and that do not require warnings (including misbranding or adulteration), qualifications, conditions (labeling restrictions), or involve another FDA regulated program, e.g., drugs or biologics, or another federal office (i.e., EPA, CPSC, DOE), or otherwise do not require a unique response, should be approved by and bear the signature of the Division Director. Also, there are special routine letters that are frequently used for a few specific devices within a Division that should be signed by the Division Director. For example, a special routine letter is used for some orthopedic implants that places limitations on the labeling for the device (e.g., for use with bone cement only). Prior to any use of such specific routine letters, the language and the circumstances under which they would be used must be discussed and agreed to on a case-by-case basis between the Division Director, and the 510(k) Staff and/or the POS Drug/Compliance coordinator. A list of specific routine letters approved to date that can be signed by the Division Director without discussions with the POS 510(k) Staff or the POS Drug/Compliance coordinator is attached (attachment 2). Signed letters should then be forwarded by the Division to the 510(k) DMC for dating, checking of the reference list and class III GMP inspection program and issuance.

4. Conditional Substantial Equivalency Device Kits or Unique Responses (Includes devices with questions/issues regarding a drug, biologic, other non-medical device or misbranding or adulteration or a device requiring postmarket surveillance)

Responses to premarket notifications that require unique responses, for example, devices that have a drug or biologic, a device requiring postmarket surveillance or other issue (including determination of a general purpose article, organ/tissue transport

media, preamendments status, or non-device status) will be prepared for the signature of the Division Director. Such premarket notifications must be discussed with and cleared by the POS 510(k) Staff and/or Drug/Compliance Coordinator before the final decision letter issues. Signed letters should be forwarded to the 510(k) DMC with the appropriate closeout code noted on the review memorandum (see attachment 3) for dating and issuance.

5. Not Substantially Equivalent/Unable to Determine Responses

Responses to premarket notifications for devices that are found to be not substantially equivalent (NSE) are to be prepared for the signature of the Division Director. Such premarket notifications should be discussed and cleared by the POS 510(k) Staff before the final decision letter issues. Signed letters should be forwarded to the 510(k) DMC for dating and issuance (no reference list or class III/GMP needed).

6. Devices with New Technological Characteristics

Decisions on devices that have new technological characteristics that have not been previously found substantially equivalent must be discussed with the POS 510(k) Staff at the earliest opportunity and certainly before preparing any correspondence. Correspondence for such devices will be prepared for the signature of the Division Director.

7. Other Decisions or Correspondence After a Final Decision

All other decisions or correspondence after issuance of a final decision (SE, NSE, Exempt, and etc.) will not be prepared before they are discussed with the POS 510(k) Staff. These decisions will include, but are not limited to, responses to an appeal of a decision, recission of a decision or clarification of a decision. These letters will be prepared for and bear the signature of the Deputy Director of ODE. These letters should be forwarded to the POS 510(k) Staff for processing out.

Effective Date: This memorandum is effective immediately.

Susan Alpert, Ph.D., M.D.

Attachments

Attachment 1 (June 1, 1994)

Summary of Premarket Notification Sign-Off and Processing Procedures

Decision Type	Approved By	POS Discussion/ Clearance Drug/ Compliance Coord.	Division Forward Letter To
I. Unable to Determine Substantial Equivalence/ Request for Additional Information Response			
a. can be responded to in 30 days or less	Branch Chief	No	510(k) DMC
b. cannot be reponded to in 30 days or less	Division Director	No	510(k) DMC
II. Device Exempt by regulation from premarket notification Response	Division Director	No	510(k) DMC
III. "Standard" Substantial Equivalency Responses	Division Director	No	510(k) DMC
IV. "Conditional" Substantial Equivalency or Unique Response	Division Director	Yes	POS 510(k) DMC
V. Not Substantially Equivalent Responses	Division Director	Yes	POS 510(k) DMC
VI. Devices with New Technological Characteristics	Division Director	Yes	POS 510(k) DMC

VII.	All letters after insurance of any final decision (SE, NSE, exempt, etc.)	Deputy Director	Yes	POS 510(k) Staff

Attachment 2 (June 1, 1994)

Routine Letters Signed by ODE Division Directors

DCLD - None

DCRND - None

DOD - None

DRAERD - 1) In vitro Fertilization Disclaimer
2) Ultrasound/Transducer Model Letter

DGRD - 1) Orthopedic Implants with Bone Cement
2) Wound Dressings
3) Surgical Gloves - Dusting Powder
4) Lasers - Electronic Language
5) Cannulas and Aspirators - Suction Lipectomy

Attachment 3 (June 1, 1994)

510(k) DECISION CODES

Signature Block	Substantially Equivalent Codes
DD - SP	Substantially Equivalent - Postmarket Surveillance-5/92
DD - KD	Substantially Equivalent - Kit with Drugs-8/89
DD - RN	Substantially Equivalent - Rescind Non-Substantial Equivalence-8/89
DD - SD	Substantially Equivalent with Drug
DD - SE	Substantially Equivalent
DD - SK	Substantially Equivalent - Kit-8/89
DD - SL	Substantially Equivalent - Improper Label
DD - SN	Substantially Equivalent for Some Indications
DD - SW	Substantially Equivalent waiting on a drug-11/90
DD - SI	Substantially Equivalent waiting on inspection
DD - SA	Substantially Equivalent waiting on a device-12/91
DD - PR	Proposed Rescission
DD - SF	Substantially Equivalent waiting on future policies
DD - SO	Substantially Equivalent - not subject to CLIA categorization
DD - SX	Substantially Equivalent - CLIA categorization waived
DD - SM	Substantially Equivalent - moderate CLIA category
DD - SH	Substantially Equivalent - high CLIA category
DD - ST	Substantially Equivalent - Tracking Regulation
DD - PT	Substantially Equivalent - Post Market Surveillance - Tracking Regulation

Non-Substantially Equivalent Codes

DD - NE	Not Substantially Equivalent
PJP - RE	Rescind Substantial Equivalence
UD	Unable to Determine Equivalence - no longer used after 9/30/87
DD - SC	Pre-amendment Investigational - Cannot Market (prior to 7-1-91 counted as an "SE")
DD - UO	Unable to Determine Equivalence - Outstanding Drug Issue
DD - OD	Outstanding Device - Unable to Determine Equivalence
DD - SL	Substantially Equivalent - Improper Label (5-12-92)
DD - UR	Unreliable Data (Fraud Policy)-5/92
DD - FB	515(B) Requires PMA
DD - DA	Did not Answer

Other Decision Codes

DD - DB	Forwarded to Drugs/Biologics (letter 1/91)
MS - DD	Deleted/Duplicate
MS - DE	Deleted
DD - EX	Exempted by Regulation
DD - GP	General Purpose Article-7/89
DD - K4	Closeout Letter Issued
DD - ND	Not a Device
DD - NF	Not a Finished-7/89
DD - NA	Not Actively Regulated-7/89
DD - TR	Transitional Device
MS - WD	Withdrawn by Applicant
DD - NR	Not Required
HO	Codes no longer used; once used to
SP	Indicate "On Hold" or "Supplement Received"
DD - DR	Drug due to Intercenter Agreement-3/92
DD - PE	Preamendment Exempt-6/92
DD - CR	Can't Respond within 30 days
DD - RC	Reconditioners/Rebuilders-11/93

Legend

PJP - Deputy Director, ODE (Philip J. Phillips, Acting)
MS - Supervisor, Document Mail Center (Marjorie Shulman)
DD - Division Director, OD

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)