Cover Letter: 510(k) Requirements During Firm-Initiated Recalls; Attachment A: Guidance on Recall and Premarket Notification Review Procedures During Firm-Initiated Recalls of Legally Marketed Devices (blue book memo #K95-1) (Text Only)

510(k) Requirements During Firm-Initiated Recalls

510(k) Memorandum #K95-1

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.

November 21, 1995

Director
Office of Device Evaluation

510(k) Requirements During Firm-Initiated Recalls

ODE Review Staff
Through: ODE Branch Chiefs

Purpose

The purpose of this memorandum is to implement the procedures embodied in the attached guidance for the Office of Compliance and the Office of Device Evaluation concerning recall and premarket notification review procedures during a firm-initiated recall of a legally marketed device.

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Background

When a firm initiates a recall of a device, the firm's recall strategy may include a proposal to modify the device to correct the cause of the recall. In the past, the Office of Compliance (OC) asked the Office of Science and Technology to conduct a preliminary assessment of the proposed correction. If the correction appeared to be appropriate, the Center exercised enforcement discretion and allowed the firm to implement the correction for units of the device that were already distributed. If the modification was of a type that required a new premarket notification, the firm generally had to submit a premarket notification and obtain clearance from the Office of Device Evaluation (ODE) before implementing the correction for any new production. This process involved redundant reviews and potentially conflicting assessments of the same modification, and could unnecessarily delay corrections of defective devices.

The document in Attachment A, entitled "Guidance on Recall and Premarket Notification Review Procedures During Firm-initiated Recalls of Legally Marketed Devices" was signed by the Directors of OC and ODE on October 27, 1995. It contains standard operating procedures that are designed to eliminate redundancy in reviews and streamline the overall process. This guidance was developed by an ad hoc committee within CDRH. The guidance was the subject of review at two Center

"poststaff" meetings at which input and comments were received from all Center offices, as well as meetings of OC's and ODE's senior staff. In addition, it has been discussed with several medical device trade associations and has been the subject of public discussion.

Procedures

The new procedures that will be followed within OC and ODE are set forth in the attached guidance. A flow chart for these procedures, entitled "510(k) Requirements for Proposed "Fixes" to Devices Undergoing Recall," appears in Attachment B. If you have any questions concerning the application of these procedures to a specific situation you may have, please contact the 510(k) Staff, ODE, for additional guidance.

Effective Date

This memorandum is effective immediately.

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

510(k) Memorandum - #K95-1

October 27, 1995

Guidance on Recall and Premarket Notification
Review Procedures During Firm-Initiated
Recalls of Legally Marketed Devices

Applicability and Purpose

This procedural guidance applies to recall actions in which a firm notifies the Food and Drug Administration (FDA) that it intends to modify a legally marketed device (as defined in 21 CFR 807.92(a)(3)) to correct the cause of a recall. If the correction proposed by the firm will alter the device rather than just restore it to its original specifications, there is a potential for redundant review of the correction within the Center for Devices and Radiological Health (CDRH) through both the recall process and the premarket notification (510(k)) process. The purpose of this guidance is to encourage timely corrections of defective devices by clarifying which process CDRH will use to review such modifications and by eliminating redundant procedures in cases where both processes apply. This document supersedes guidance on this topic provided in a June 29, 1994 memorandum from the former director of CDRH's Office of Compliance (OC) to OC staff.

This guidance is not intended to apply to: recall actions for devices that were introduced to the market without proper premarket clearance; corrections that FDA is informed of retrospectively rather than before they are made; or situations that are not bona fide recalls.

Approach

The attached chart summarizes the decision process that CDRH will use to determine whether the review of a proposed correction will be conducted solely through the recall process or with the 510(k) process. The basic intent is to avoid duplicative review of proposed device corrections. OC has overall responsibility within CDRH for

coordinating the recall decision process, while the Office of Device Evaluation (ODE) is responsible for making certain decisions specified in the attached chart.

During a recall action, OC's case officer will review the firm's recall strategy to determine if the firm's corrective actions include a proposed modification to the device. In making this determination, OC's case officer will consider whether a correction alters the device rather than just restoring it to its original specifications. If the correction just restores the device to its original specifications (e.g., a correction involving good manufacturing practices), OC's case officer will determine that the recall does not involve a modification to the device. In this case, no 510(k) issue is involved and OC's case officer will process the recall accordingly. On the other hand, if the firm's recall strategy includes a correction that may alter the device, OC's case officer will ask the appropriate ODE division to assess whether the proposed modification requires a 510(k) submission.F CDRH is currently developing guidance on how to determine whether a device modification requires a 510(k) submission. When the guidance is available, ODE will refer to it in making this decision.

ODE will consider whether the modification could significantly affect safety or effectiveness (per 21 CFR 807.81(a)(3)). Because recalls usually involve situations that present risks to health, modifications intended to correct the cause of a recall usually will satisfy this criterion. Thus, corrections that alter the indications for use, design, or performance specifications of a device usually will require a 510(k) submission. If, however, ODE determines that the modification could not significantly affect safety or effectiveness, no 510(k) submission will be required and OC's case officer will process the recall accordingly.

The following procedures will be used to assess a proposed correction that requires a 510(k) submission. In general, ODE will attempt to assess the correction during the recall process, and will not repeat this assessment when reviewing the 510(k) submission.

- Special 510(k) -- Corrective Action Being Effected. During the recall process, ODE (with input from other offices, if appropriate) will attempt to assess whether the modification appears to be an adequate correction, and whether the

modified device will be "substantially equivalent." This approach is conditioned upon the firm providing sufficient information to assess the proposed modification during the recall process. If ODE believes that the proposed modification is appropriate, OC will inform the firm of this assessment and will instruct the firm to submit a "Special 510(k) -- Corrective Action Being Effected." ODE will conduct only an abbreviated review of the 510(k), and will strive to complete the review within 30 days. The purpose of the abbreviated review will be to ensure that the 510(k) submission is administratively complete, and that it includes only the modification(s) already found acceptable by CDRH as part of the recall process. While 510(k) clearance is pending, CDRH will exercise enforcement discretion and allow the firm to implement the modification (both retrofitting and new production).

- Traditional 510(k). The above approach will not be used if sufficient information to assess the modification is not readily available from a firm during the recall process (such as when extensive testing is needed). In this case, OC will inform the firm that review of the modification will be conducted through the 510(k) process rather than the recall process, and that the firm may not market the modified device (retrofitting or new production) until 510(k) clearance is obtained. If the firm requests expedited 510(k) review because there is an urgent need for the device, and ODE agrees that there is an urgent need, ODE will expedite review of the 510(k) submission. In the absence of an urgent need, the 510(k) submission will be reviewed according to the "first-in, first-reviewed" policy normally applicable to 510(k) submissions.

Effective Date

This guidance takes effect upon issuance. Questions on the interpretation of this guidance should be directed to Heather Rosecrans, ODE, or John Samalik, OC.

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Susan Alpert, Ph.D., M.D.	Lillian Gill
Director, ODE	Director, OC

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Attachment B - Page 1

510(k) Requirements for Proposed "Fixes" to Devices Undergoing Recall

- **Attachment B (/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm080298.pdf)** (Adobe PDF)

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)