Medical Device Reporting – Remedial Action Exemption; Guidance for Industry and FDA

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This document supersedes MDR Guidance Document: Remedial Action Exemption E 1996001 dated July 30, 1996

U.S. Department Of Health And Human Services
Food and Drug Administration
Center for Devices and Radiological Health

Reporting Systems Monitoring Branch
Division of Surveillance Systems
Office of Surveillance and Biometrics

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Dockets Management Branch, Division of Management Systems and Policy, Office of Human Resources and Management Services, Food and Drug Administration, 5630 Fishers Lane, Room 1061, (HFA-305), Rockville, MD, 20852. When submitting comments, please refer to the exact title of this guidance document. Comments may not be acted upon by the Agency until the document is next revised or updated.

For questions regarding the use or interpretation of this guidance contact Sharon Kapsch, Reporting Monitoring Branch at (301) 594-2735, by FAX at (301) 827-0038 or email at rsmb@cdrh.fda.gov or mail at:

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MEDICAL DEVICE REPORTING GUIDANCE DOCUMENT REMEDIAL ACTION EXEMPTION

This document is intended to provide guidance. It represents the Agency's current thinking on this topic. It does not create or confer any rights for or on any person and does not operate to bind the Food and Drug Administration (FDA) or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute, regulations, or both.

INTRODUCTION

The Medical Device Reporting (MDR) Regulation (21 CFR 803) requires that you report adverse events for products undergoing remedial action. This document offers guidance to request an exemption under 21 CFR 803.19 for reporting certain adverse events that involve device remedial action. FDA intends to grant this exemption for manufacturers when they provide information that indicates additional reports about a device that already has been the subject of a remedial action will not provide any significant new data.

THE LEAST BURDENSOME APPROACH

We believe we should consider the least burdensome approach in all areas of medical device regulation. This guidance reflects our careful review of the relevant scientific and legal requirements and what we believe is the least burdensome way for you to comply with those requirements. However, if you believe that the information requested in the guidance is not relevant to the decision-making process or that an alternative approach would be less burdensome, please contact us so we can consider your point of view. You may send your written comments to the contact person listed in the preface to this guidance or to the CDRH Ombudsman. Comprehensive information on CDRH's Ombudsman, including ways to contact him, can be found on the Internet at http://www.fda.gov/cdrh/resolvingdisputes/ombudsman.html.

What are the criteria for the Remedial Action Exemption (RAE)?

As a medical device manufacturer, you may request an exemption from the requirement to report certain adverse events associated with medical device remedial actions, if *all* of the following conditions apply:

(1) You submit an RAE notification to us. Your RAE notification must be filed with or after submission of one or more 5-day or 30-day initial reports on events that are subject to a remedial action to be covered under this exemption. Your MDR report(s) must be filed within the required timeframe and cannot be delayed in order to be included in an RAE notification. You cannot utilize this exemption until at least one applicable MDR report is sent to us. All required baseline reports must also be filed with the 5-day or 30-day report.

(2) You notify the appropriate FDA District Office of the remedial action prior to or at the time of submission of the RAE notification.

(3) You conduct a complete complaint investigation as required by the Quality System Regulation (21 CFR 820).

(4) Your RAE notification references this exemption and states that future incidents meeting all of the conditions will not be reported to us. Your notification should include all of the following information:

(a) the identity of the FDA District Office that you informed (including the name and address of the person contacted) about the remedial action,

(b) the date and method used to inform the District Office,

(c) a description of the nature of the notification to customer, such as a letter,

(d) the range of device model numbers, catalog numbers, serial numbers, or lot numbers covered by the remedial action,

(e) a complete description of the reported problem, including specific components as appropriate, that adequately explains why the product is undergoing a remedial action, and

(f) the manufacturer MDR report number(s) for the initial 5-day or 30-day MDR report filed for the remedial action, or a statement that the MDR that triggered the 5-day or 30-day report is attached to the RAE.

What can I do to extend my RAE ?

If the remedial action is extended beyond the product originally corrected, then additional

information about your extension should be submitted in writing to CDRH and the appropriate District Office as a supplement to the original "Remedial Action Exemption" notification.

If adverse event reports indicate new problems, distinct from those described in the RAE notification, then you must report the events under the regular MDR reporting requirements until a new remedial action begins and you have submitted a new RAE request.

Send your Remedial Action Exemption notification to the following address:

Food and Drug Administration
Center for Devices and Radiological Health
Medical Device Reporting
P.O. Box 3002
Rockville, MD 20847-3002

Direct your Remedial Action Exemption questions to:

RSMB@CDRH.FDA.GOV
Fax # 301-827-0035
Phone # 301-594-2735

In accordance with 21 CFR 803.19 (d), FDA may revoke or modify your Remedial Action Exemption at any time if it determines that protection of the public health justifies such revocation or modification.