Guidance for Industry and CDRH Reviewers

1-Consolidated Annual Report for a Device product line (1-CARD)

Pilot for preparation of annual reports for pacemaker premarket approval applications[1]

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

Pacing and Electrophysiology Devices Group
Division of Cardiovascular and Respiratory Devices
Office of Device Evaluation

Preface

Public Comment

Comments and suggestions may be submitted at any time for Agency consideration to Mitchell Shein, Director, Division of Cardiovascular and Respiratory Devices, Office of Device Evaluation, HFZ-450, 9200 Corporate Blvd., Rockville, MD 20850. 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 Mitchell Shein at (240) 276-4080 or email Mitchel.Shein@fda.hhs.gov.

Additional Copies

Additional copies are available at the World Wide Web/ CDRH/ home page: http://www.fda.gov/cdrh/ode/guidance/1167.pdf or CDRH Facts on Demand at 1-800-899-0381 or 301-827-0111, specify number 1167 when prompted for the document shelf number.

1-Consolidated Annual Report for a Device product line (1-CARD)[1]
Pilot for preparation of annual reports for pacemaker premarket approval applications

Introduction

The purpose of this document is to provide guidance to industry on an alternate method for fulfilling postapproval reporting requirements as spelled out in the "CONDITIONS OF APPROVAL FOR CARDIAC PACEMAKERS AND PROGRAMMERS".

This alternative method, "1-CARD", allows a manufacturer to submit one consolidated annual report per year which includes information on many (or all) of the devices in an entire pacemaker product line. This complete single consolidated annual report will meet the regulatory requirements for all of the PMA or PDP applications listed in the report. This alternate reporting method will be piloted for cardiac pacemakers. However, if successful, it could be extended to other devices or device types.

The intent of this program is:

• to reduce the regulatory burden on industry and FDA of preparing and reviewing multiple annual reports for devices that only slightly vary in design, performance, and intended use;

• to reduce duplication of information in cases where changes in manufacturing or components effect many PMA (and/or PDP) applications; and

• to more easily identify device component or manufacturing problems that may affect multiple PMA (and/or PDP) applications.

Suggested Reporting Format

1. Number of Copies to be submitted

Two copies of each 1-CARD submission should be submitted to PMA Document Mail Center (HFZ-401), Center for Devices and Radiological Health, Food and Drug Administration, 9200 Corporate Boulevard, Rockville, Maryland 20850. The submission should be clearly identified as an "Annual Report", referencing the PMA (or PDP) numbers of all of the pacemaker models to be included.

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[1]This document is intended to provide guidance. It represents the Agency's current thinking on the above. It does not create or confer any 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.

2. Cover Letter

A cover letter should be included with every 1-CARD submission. This cover letter should reference every PMA and PDP that is included in the 1-CARD submission, and should provide a table or chart to indicate which pacemaker (both by trade name and model number) is covered by which PMA (and/or PDP) application. It is suggested that the manufacturer supply a "family tree" which presents their product line in a hierarchical format starting from platform (products with a common hybrid) and showing a mapping to product family and model name.

The cover letter should also state the beginning and ending dates of the period of time covered in the report.

For ease of record keeping, FDA asks that the submitter supply one copy of the cover letter for each PMA or PDP referenced by the 1-CARD report. For example, if seven PMA's are collectively referenced and reported on, seven copies of the cover letter should be submitted to the Document Mail Center.

3. Pacemaker Performance

FDA suggests that the manufacturer report on pacemaker survival probability both graphically and in a tabular format. FDA requests that device models and families be grouped by platform name and model family name, and that devices be referred to by trade name, rather than model number.

One suggested format for the graphical presentation is to display the survival probability (Device Survival Probability % vs. Years After Implant) in four figures:

Single Chamber Pacemakers: Currently Commercially Available
Single Chamber Pacemakers: No Longer Commercially Available
Dual Chamber Pacemakers: Currently Commercially Available
Dual Chamber Pacemakers: No Longer Commercially Available

A separate tabular survival probability table should be provided for single and dual chamber pacemakers. For each platform, device family name, or model name, the following data should be provided:

- Number of registered implants
- Number of active implants
- Number of pacemakers domestically implanted during the year as well as the number of reported explants and deaths (verified by national death indexes, credit reporting bureaus, etc.)
- Number of pacemakers exhibiting Elective Replacement time Indication
- Number of failures
- Actuarial survival probability reported at one year intervals through year ten, and at two year intervals thereafter.

4. Reportable changes

All 1-CARD submissions shall identify changes described in 21 CFR 814.39(a), and changes required to be reported to FDA under 21 CFR 814.39(b). In cases where the change affects more than one PMA (or PDP), the change need only be reported once, however, the report should cite each platform, family, or model name affected by the change, as well as the applicable PMA (and/or PDP) supplement numbers.

5. Analysis of deaths, explants and units returned for cause

For each platform, device family, or model, the report should provide the following:

a. The number of deaths should be reported and broken down into pacemaker related and non-pacemaker related.

b. The number of reported explants should be broken down into those reported at the end of battery life, those having complications unresolvable by programming and those explanted for other reasons. Reasons for explant should be reported and broken down as to cause. Failures and the mode of failure should be clearly described. If a failed component or software module is contained in other platforms, device families or models, these other models should be identified along with an analysis as to whether or not the other models are affected by the failure mode. Failures found in a component or software module that affect more than one platform, family, or model need only be reported one time, as long as each affected model of family of devices is listed. Any remedial action taken to correct a pattern of failures should be clearly explained.

c. The number of pacemakers from domestic sources returned for cause should be provided, along with a breakdown into the number of those currently in analysis, those operating properly, those at normal battery depletion, and those failed, with the failure mechanisms described. If a failed component or software module is contained in other device models or families, these other models should be identified along with an analysis as to whether or not the other models are affected by the failure mode and why or why not. Failures found in a component or software module that affect more than one model or family need only be reported one time, as long as each affected model of family of devices is listed. Any remedial action taken to correct a pattern of failures should be clearly explained.

6. Programmers

The report should contain the number of programmers shipped (by model name and number) and the number of returns with a breakdown into the numbers currently in analysis, operating properly, and failed, with the failure mechanisms described.

7. Advisories, Safety Alerts and Recalls

The 1-CARD submission should summarize all advisories, safety alerts and product recalls affecting any of the devices covered by this report throughout the history of the PMAs or PDPs involved. This information is requested so that FDA may properly evaluate whether a device issue has been adequately addressed. For each advisory, safety alert, and recall, the submission should clearly describe:

a. The problem, its cause and possible clinical consequences;

b. The affected platforms, device families and models; and

c. Remedial action taken and/or patient management recommendations made.

8. Bibliography and Summary of Unsubmitted Reports

The report should contain a bibliography as well as a summary of information not previously submitted as part of any PMA or PDP, including:

a. unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the devices contained in this report or related devices; and

reports in the scientific literature concerning the device.