§ 820.100 Corrective and Preventive Action

Subpart J—Corrective and Preventive Action

§ 820.100 Corrective and preventive action.

(a) Each manufacturer shall establish and maintain procedures for implementing corrective and preventive action. The procedures shall include requirements for:

1. Analyzing processes, work operations, concessions, quality audit reports, quality records, service records, complaints, returned product, and other sources of quality data to identify existing and potential causes of nonconforming product, or other quality problems. Appropriate statistical methodology shall be employed where necessary to detect recurring quality problems;

2. Investigating the cause of nonconformities relating to product, processes, and the quality system;

3. Identifying the action(s) needed to correct and prevent recurrence of nonconforming product and other quality problems;

4. Verifying or validating the corrective and preventive action to ensure that such action is effective and does not adversely affect the finished device;

5. Implementing and recording changes in methods and procedures needed to correct and prevent identified quality problems;

6. Ensuring that information related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of such product or the prevention of such problems; and

7. Submitting relevant information on identified quality problems, as well as corrective and preventive actions, for management review.

(b) All activities required under this section, and their results, shall be documented.

Subpart K—Labeling and Packaging Control

§ 820.120 Device labeling.

Each manufacturer shall establish and maintain procedures to control labeling activities.

§ 820.130 Device packaging.

Each manufacturer shall ensure that device packaging and shipping containers are designed and constructed to protect the device from alteration or damage during the customary conditions of processing, storage, handling, and distribution.

Subpart L—Handling, Storage, Distribution, and Installation

§ 820.140 Handling.

Each manufacturer shall establish and maintain procedures to ensure that mixups, damage, deterioration, contamination, or other adverse effects to product do not occur during handling.

§ 820.150 Storage.

(a) Each manufacturer shall establish and maintain procedures for the control of storage areas and stock rooms for product to prevent mixups, damage, deterioration, contamination, or other