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Guidance for Industry on General/Specific Intended Use

Introduction

This guidance[1] document identifies the general principles that will be considered by the Food and Drug Administration (FDA) in determining when a specific indication for use is reasonably included within a general indication for use of a medical device[2] for purposes of determining substantial equivalence under Section 513(f) or Section 520(l) of the Federal Food, Drug and Cosmetic Act (the Act). This guidance is issued in accordance with new Section 513(i)(1)(F) of the Act, which was added by Section 206 of the Food and Drug Administration Modernization Act of 1997 (FDAMA).

There are a number of reasons medical device manufacturers may seek to add a specific indication for use to a general use of a legally marketed predicate device. In some cases, technology may drive a manufacturer's decision to request the addition of a specific indication for use; "minor" technological changes to a device may make it more applicable to one specific indication for use and less applicable to other uses. Alternatively, a new competing device may enter the market with a specific claim resulting in a potential loss of market share for the device without that claim. Sometimes the identification of a specific intended use is the result of the evolution of medical practice once a device is marketed. When the medical community adopts a specific indication for use as routine practice, manufacturers and physicians want that specific indication for use to appear on the labeling for both liability and reimbursement purposes.

Purpose

The purpose of this document is to help medical device manufacturers understand the principles used by FDA to determine whether the addition of a specific indication for use to a medical device cleared for marketing with a general indication for use could trigger the need for a PMA. The guidance is intended to help manufacturers answer the following questions: Under what circumstances is a device with a new, specific indication for use likely to be found