Arnall Golden Gregory LLP

Client Alert

Contact Attorney Regarding This Matter:

William H. Kitchens
404.873.8644 - direct
404.873.8645 - fax
william.kitchens@agg.com

Clark G. Sullivan
404.873.8512 - direct
404.873.8512 - fax
clark.sullivan@agg.com

FDA Issues Proposed Rule on Device Classification Requests

On April 29, 2010, the Food and Drug Administration (FDA) issued two draft guidance documents to help firms make better use of the FDA's device classification program (commonly referred to as "the 513(g) program") when requesting the FDA's opinion on how their device should be classified.[1] The FDA is seeking comments on both draft guidances until July 28, 2010.

Background

Section 513(g) of the Federal Food, Drug, and Cosmetic Act (FDC Act) sets forth a mechanism for obtaining FDA's views about how a medical device should be classified, and the regulatory requirements applicable to a device.[2] Companies may file written requests (referred to as "513(g) requests") to obtain a statement as to the classification of their product, such as whether the product is regulated as a medical device, whether the product is exempt from the premarket notification process, or whether the FDA will require a premarket notification (under section 510(k) of the FDC Act) or a Premarket Approval Application (PMA) for a particular device. Within 60 days of receiving a 513(g) request, the FDA is obligated to provide a written statement about the classification of the device and applicable requirements. Under the Medical Device User Fee Amendments of 2007 (Public Law 110-85), the FDA has the authority to collect user fees from section 513(g) requestors.

Draft Guidance on Procedures for Section 513(g) Requests for Information

With respect to the contents of a 513(g) request, the FDA states that the request should include the following:

- a cover letter that identifies it as a "513(g) Request for Information." The cover letter should also include:
  1. the date of the request;
  2. the name of the device;

1 *Draft Guidance for Industry and Food and Drug Administration Staff; Food and Drug Administration and Industry Procedures for Section 513(g) Requests for Information Under the Federal Food, Drug, and Cosmetic Act*, 75 Fed. Reg. 22599 (April 29, 2010). See http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/UCM209851.pdf.
Draft Guidance for Industry and Food and Drug Administration Staff; User Fees for 513(g); Requests for Information; Availability, 75 Fed. Reg. 22601 (April 29, 2010). See http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm209852.htm.

2 21 U.S.C. § 360c(g)

Arnall Golden Gregory LLP
Attorneys at Law
171 17th Street NW
Suite 2100
Atlanta, GA 30363-1031
404.873.8500
www.agg.com

3. specific question(s) concerning the class in which a device has been classified and/or the regulatory requirements applicable to a device;
4. the 513(g) requestor's contact information (e.g., name, address, telephone number, fax number, and email address); and
5. the 513(g) requestor's signature;

- a device description, which provides:
  1. a list of materials and components used in or with the device;
  2. photographs, engineering drawings and/or samples of the device;
  3. a summary of the device's operational principles;
  4. a description of the type and amount of energy to be used by the device; and
  5. a description of similar devices in commercial distribution in the United States;
- a use description of the device, which describes:
  1. the disease or condition intended for the device;
  2. prescription versus over-the-counter use of the device;
  3. the part of the body or type of tissue applied to or interacted with the device;
  4. frequency of use of the device;
  5. physiological purpose of the device;
  6. patient population associated to the device; and
  7. any other labeling information related to the patient use of the device; and
- proposed labeling or promotional material for the device.

The draft guidance notes that companies can, before making a 513(g) request, first obtain information about device classification and regulatory requirements on the FDA's website, including the agency's product classification, 510(k), and PMA databases; and a list of Class I and II devices exempt from 510(k) requirements. If the requestor is still unsure about which center at the FDA has the authority over the product (e.g., a combination product, such as a drug-device combination), the guidance suggests the requestor to contact the FDA's Office of Combination Products and determine whether to submit a formal Request for Designation rather than making a 513(g) request.[3]

Regarding limitations of the 513(g) process, the draft guidance states that:

- 513(g) responses are not classification decisions and do not constitute FDA clearance or approval for marketing. The most common method of seeking a classification decision is to submit a premarket notification under section 510(k) of the FDC Act. 513(g) responses will generally indicate:
  1. the device's generic type;
  2. the class of the device within that generic type;
  3. whether a PMA, 510(k) or neither is required; and other additional applicable requirements.
- FDA does not review data related to substantial equivalence or safety and effectiveness in 513(g) requests.

3 e.g., Center for Device and Radiological Health (CDRH), and Center for Biologics Evaluation and Research (CBER).

- Once a 513(g) request is submitted to FDA with the requisite user fees, subsequent addition of a new question, use, or technology to the pending Request for Information will be considered as a new 513(g) request, which will be subject to an additional user fee and be responded separately by FDA.

Draft Guidance on User Fees for Section 513(g) Requests for Information

The FDA makes the following points with regard to user fees:

- All 513(g) requests are subject to user fees, and there is no exception for devices intended solely for pediatric patients, or requestors who are state or federal government entities.
- User fees for 513(g) requests were $2,710 in fiscal year 2009 ($1,355 for small businesses), and rose to $2,941 in fiscal year 2010 ($1,470 for small businesses).[4]
- The FDA will refund the fee if it determines that the submission was not a 513(g) request for information, but it will not refund the fee if it turns out the product is not a medical device or that the product is exempt from premarket notification.[5]
- The FDA will not refund the fee if the 513(g) request is withdrawn.
- If a 510(k) or a PMA submission is submitted following a 513(g) request, the company must pay user fees associated with the new submission without any discount or credit from the user fees paid for the prior 513(g) request.
- Information submitted in response to an FDA request for additional information is not considered as an addition of a new question, use, or technology to the pending 513(g) request and, therefore, does not require an additional fee payment.

In summary, the FDA intends to encourage companies to make better use of 513(g) requests, because the process seems to be misunderstood and misused. The FDA recommends that companies conduct a preliminary study of their product based upon the device classification information on FDA's website to avoid unnecessary 513(g) submissions.

4 Reported gross receipts or sales (including all affiliates) are $100 million or less for the most recent tax year.
5 Submissions that do not request information respecting the class in which a device has been classified or the requirements applicable to a device under the FDC Act will be considered as non-513(g) requests.

Mr. Kitchens and Mr. Sullivan would like to thank Andrew Zhang who assisted significantly with the preparation of this article. Mr. Zhang is a recent law school graduate and an employee of Arnall Golden Gregory LLP in our life sciences practice. Mr. Zhang is not yet admitted to the State Bar of Georgia.