



March 18, 2010

Division of Dockets Management (HFA-305)  
Food and Drug Administration  
5630 Fishers Lane, Room 1061  
Rockville, MD 20852

**Re: Strengthening the Center for Devices and Radiological Health's 510(k)  
Review Process; Request for Comments (Docket No. FDA-2010-N-0054)**

Dear Sir or Madam:

The American Association for Justice (AAJ), formerly known as the Association of Trial Lawyers of America (ATLA), hereby submits comments in response to the Food and Drug Administration's (FDA) Notice regarding strengthening the 510(k) review process. *See* 75 Fed. Reg. 4402.

AAJ, with members in the United States, Canada and abroad, is the world's largest trial bar. It was established in 1946 to safeguard victims' rights, strengthen the civil justice system, promote injury prevention, and foster the disclosure of information critical to public health and safety. AAJ applauds the FDA's efforts to strengthen the 510(k) process. The vast majority of medical devices that are approved for use in the United States go through the 510(k) clearance process. Unfortunately, this process has not been as vigorous and robust as necessary to protect the safety and health of patients.<sup>1</sup>

**I. Lack of Accuracy in 510(k) Clearance Applications Is Detrimental to Patient Safety**

**A. The FDA Must Ensure 510(k) Submitters Are Submitting Accurate Information**

Since the FDA is relying only on what is contained within each application to approve a medical device and not on separate testing, it is extremely important that each application is accurate. The FDA is unable to verify the veracity of the information contained in a 510(k) application in real time, and if an inaccurate application gets cleared, an unsafe device could

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<sup>1</sup> The FDA should continue to make clear, in any guidance issued as a result of this Notice, that state tort claims remain available to patients who are injured by a 510(k) cleared device and are not preempted. *Medtronic, Inc. v. Lohr*, 51 U.S. 470 (1996).

reach the marketplace and harm patients.<sup>2</sup> AAJ believes that device manufacturers should be held responsible for any determined inaccuracies in 510(k) applications. As such, similar provisions to the recently proposed regulations on reporting information regarding falsification of data should be applicable to the 510(k) process.<sup>3</sup> The FDA should require that 510(k) submitters notify the FDA within 45 days of when they know, or should have known, that information provided in a 510(k) application is inaccurate. If a 510(k) submitter fails to notify the FDA of an inaccuracy within a timely fashion, the 510(k) submission in question should be denied or rescinded and the submitter should be fined. In order to protect patient safety it is essential that the FDA hold 510(k) submitters responsible for inaccuracies in applications.

**B. The FDA Must Ensure that 510(k) Submitters Have the Necessary Resources In Order to Submit Accurate Applications**

In addition to holding 510(k) applicants responsible for the information provided during the 510(k) clearance process, the FDA should strive to ensure that 510(k) database is current, easily searchable, clear and provides enough information so that applicants are able to accurately research and draft submissions.<sup>4</sup> Most 510(k) submitters rely on the database to garner information regarding predicate devices and substantial equivalence. If the database is not maintained and updated regularly submitters may not be relying on accurate information for their submissions. Additionally, the FDA should ensure that any inaccurate information contained in the database is removed in a timely fashion so that future submitters do not rely on it. The FDA must take whatever actions are necessary to ensure that the database of information on which 510(k) applications are based is available, accurate and easy to use in order to improve the safety of medical devices.

**II. The FDA Must Provide More Than One Reviewer Per 510(k) Application**

**A. One Reviewer Per 510(k) Application Can Cause Mistakes That Result in Patient Injury or Death**

Each person who wants to market a Class I, II, and III device intended for human use in the United States, for which a Premarket Approval (PMA) is not necessary, must submit a 510(k) to FDA.<sup>5</sup> The 510(k) essentially acts as a fast-track for device approval because device

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<sup>2</sup> See *FDA Memo Hints at Curbs to Approval Process for Medical Devices*, Wall Street Journal, February 18, 2009, Alicia Mundy and Hared A. Favole. The article also notes that there has already been at least one rescission of a 510(k) device based on false information. *Id.*

<sup>3</sup> See 75 Fed. Reg. 7413.

<sup>4</sup> President Obama's Transparency and Open Government Memorandum supports the disclosure of information to the public in forms that are readily able to be used. See Memorandum for Heads of Executive Departments and Agencies: Transparency and Open Government, 74. Fed. Reg. 24693 (May 20, 2009).

<sup>5</sup> See 21 CFR § 862.9; See 21 CFR § 864.9.

manufacturers only must demonstrate on paper that a device is substantially equivalent to a legally marketed device. Furthermore, this fast-track process applies to medical devices whose misuse or failure could have a significant impact on patient care and safety. Accordingly, the FDA should conduct a stringent review of each 510(k) clearance application. AAJ believes that it is impossible to conduct a stringent review of a 510(k) clearance application, when only one reviewer reviews each application. By utilizing only one reviewer, the chances for error are tremendous. This practice exponentially increases the chances that a potentially harmful device is cleared for marketing. This is further exacerbated by the fact that the FDA has no clear authority at present to generally conduct post-market research on these devices. As such, the FDA should implement procedures that require review by multiple FDA employees prior to approval for marketing.

### **III. The FDA Should Strengthen Its Post-Approval Requirements for the 510(k) Process**

#### **A. The FDA Should Require Manufacturers of 510(k) Cleared Devices to Strengthen Warnings and Modify Device Design as Soon as There is Reasonable Evidence of a Serious Hazard**

Manufacturers of prescription drugs are obliged to ensure that labeling of their products “be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved.”<sup>6</sup> Similarly, all manufacturers of Class III devices should be required to strengthen warnings and modify product designs as soon as there is reasonable evidence of a serious hazard.<sup>7</sup> Devices with inappropriate warning labels pose a significant threat to the health and well being of the patients that utilize them. As such, the FDA should consider bolstering regulations regarding warning labels for devices.

#### **B. The FDA Should Be Notified of a Purchase/Sale or Transfer in Ownership of a 510(k)**

Patients should be assured of the continued safety of any medical devices approved through the 510(k) process. Accordingly, the FDA should have stronger procedures in place for monitoring devices that have been through the 510(k) clearance process. First, the FDA should require notification of purchase/sale or transfer in ownership of a 510(k) for a device. If the FDA does not have current ownership information for a 510(k), then post-market surveillance of adverse events related to a device becomes almost impossible. As such, the FDA should require that it is notified of any sale or transfer in ownership of a 510(k) for a device within thirty days.

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<sup>6</sup> 21 CFR 201.57(e).

<sup>7</sup> AAJ recognizes that the present Notice only deals with the 510(k) clearance process. Nevertheless there is an urgent need for an equivalent to the drug labeling requirement in 21 CFR 201.57(e) for all Class III devices, including those approved by the PMA process.

Companies who fail to notify the FDA of a transfer in ownership should be fined. The FDA must have ownership information on all 510(k) holders in order to assure continued patient safety.

### **C. The FDA Should Require Post-Market Surveillance Studies**

In addition to keeping apprised of the ownership interests of 510(k)'s, the FDA should require post-market surveillance studies of medical devices as a condition of the 510(k) clearance process. Although, the FDA currently does not have the explicit authority to require a post-market study as a condition of approval; we request that the FDA pursue receiving this authority. Requiring post-market study of certain devices as a part of the 510(k) clearance process is the only way to ensure the safety of many of these devices. Failing that, the FDA should consider utilizing 522 post-market evaluation orders more frequently. The FDA may "require a manufacturer to conduct post-market surveillance for any device of the manufacturer which is a class II or class III device the failure of which would be reasonably likely to have serious adverse health consequences or which is intended to be: (1) implanted in the human body for more than one year, or (2) a life sustaining or life supporting device used outside a device user facility."<sup>8</sup> In 2003 through 2007 the FDA reviewed 13,541 510(k) applications but the FDA's Post-Market Surveillance Study database currently contains just twenty-one entries dating back to 2004.<sup>9</sup> In an effort to promote the continuing safety of cleared medical devices and in the interest of patient safety, the FDA should utilize post-market surveillance as vociferously as possible under the law.

### **D. The FDA Should Allow for Rescission of a 510(k) in a Broad Set of Circumstances**

Lastly, the FDA should allow for rescission of 510(k) clearance decisions in a wide array of circumstances. There are many different instances in which it would be appropriate to rescind a 510(k) clearance. They include: new safety data or information regarding adverse events linked to the device, fraud in the clearance process and problems with the underlying clinical data that was used to clear the device. The FDA has long considered developing regulations that would allow for rescission of a 510(k) clearance under these types of situations.<sup>10</sup> In fact, in 2001 the FDA proposed regulations of this topic that were never finalized.<sup>11</sup> In the interest of patient safety, the FDA should finalize regulations that would allow for the rescission of a 510(k) in any circumstance where patient safety is jeopardized.

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<sup>8</sup> 21 U.S.C. 360l.

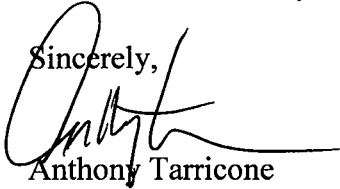
<sup>9</sup> See United States Government Accountability Office, Report to Congress, Medical Devices, January 2009; See <http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPMA/pss.cfm> as of March 12, 2010.

<sup>10</sup> 66 F.R. 3523 (2001).

<sup>11</sup> *Id.*

AAJ appreciates this opportunity to submit comments in response to the Agency's Notice regarding strengthening the 510(k) process. If you have any questions or comments, please contact Sarah Rooney, AAJ's Regulatory Counsel at (202) 944-2805.

Sincerely,

A handwritten signature in black ink, appearing to read 'Anthony Tarricone', with a long horizontal flourish extending to the right.

Anthony Tarricone

President

American Association for Justice