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Legal Insights

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Get Back to Where You Once Belonged: FDA Wins Lawsuit to Rescind 510(k)

The Food and Drug Administration recently won an important court victory that allowed the agency to rescind a medical device's premarket notification clearance (commonly referred to as a "510(k)").[1] It is too early to predict whether the decision, Ivy Sports Medicine, LLC v. Sebelius, Civil Action No. 11-ev-1006 (RCW) (D.D.C. April 10, 2013), will empower FDA to use the rescission threat in more cases or whether it's a one-off, fact-specific case that will have limited applicability. However, the holding is significant, because it supports the agency's position that it has the authority to rescind a 510(k).

In this Bulletin, we will not discuss the medical device's lengthy and interesting regulatory history, including the particulars of the procedural irregularities in the review of Ivy's original 510(k) application. Our focus will be on the court's decision and the basis for its holding, which may provide insight into those situations where FDA might choose to exercise its authority to revoke a prior substantial equivalency determination.

In this case, Ivy Sports Medicine, LLC, a predecessor company to ReGen Biologics, Inc., sued FDA when the agency changed the classification of the company's medical device (a collagen meniscus implant intended to reinforce damaged meniscus soft tissue) from a Class II to a Class III device, thereby requiring premarket approval, not merely 510(k) clearance. Previously, the agency had cleared the device's 510(k), after much internal debate, but, subsequently after the clearance, FDA reconsidered its decision based on "procedural irregularities" and the potential compromise of "the integrity of our process," and found that the device did not have the same intended use as the predicate device. After its decision to reclassify the device into Class III, it rescinded the 510(k).

The company argued in the U.S. District Court for the District of Columbia that FDA lacked legal authority to rescind a 510(k) substantial equivalence decision. Because the rescission resulted in a reclassification of the device from Class II to Class III, the company contended that FDA should have followed the reclassification procedures in 21 U.S.C. § 360c(e). The district court held that because of misconduct and numerous departures from normal agency practice during the original 510(k) decision-making process, FDA could invoke its "inherent authority" to reclassify the product, rather than being required to implement the statutory reclassification provision.

1 The case is available at http://www.gpo.gov/fdsys/pkg/USCOURTS-dcd-1_11-cv-01006/pdf/USCOURTS-dcd-1_11-cv-01006-1.pdf.

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The court rejected Ivy's argument that the FDA acted arbitrarily and capriciously, finding that the agency properly re-evaluated the device's intended use when it found technological differences between the device and the identified predicate devices. The court also held that FDA acted in a timely manner, i.e, "within a reasonable period of time," to reclassify the product. With regard to this issue, the court agreed with FDA's interpretation that the relevant time period for review began from FDA's initial determination on the 510(k) application to the time when Ivy received notice that this decision was under active reconsideration.

The court decision reaffirms what FDA has maintained for some time – it has the authority to rescind a 510(k). In a 2010 report to improve the agency, one proposal by the "510(k) Working Group," not formally adopted, was that FDA issue a regulation that allowed it to partially or fully rescind a 510(k).[2] FDA has maintained in the past that it has the authority to rescind a 510(k).[3] The recent district court decision supports FDA, but it is important to recognize the district court opinion focused on two key points: (1) FDA gave notice of reconsideration "in a reasonable time frame" and (2) there was evidence in the record of procedural irregularities and other misconduct that affected the integrity of FDA's original decision, thereby opening the door for re-consideration of the 510(k) decision. Consequently, the unusual facts of the case are not likely to reoccur often, thereby potentially limiting the holding's applicability. Nevertheless, it is a victory for FDA and another enforcement tool in its arsenal, particularly if it believes mistakes might have been made in the initial review process of a 510(k) application for a medical device.

2 See e.g., FDA, 510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps, at 13 (2010), available at http://www.fda.gov/downloads/AboutFDA/CentersOffices/CDRH/CDRHReports/UCM239449.pdf.

3 See e.g., FDA, 510(k) and Science Report Recommendations: Summary and Overview of Comments and Next Steps, at 14 (2010).