



OCT 31 2000

Food and Drug Administration  
Rockville MD 20857

Mr. Arnold Levin  
Plaintiffs' Legal Committee  
Orthopedic Bone Screw Litigation  
Suite 300 - 414 Walnut Street  
Philadelphia, Pennsylvania 19106

1574 '00 NOV -2 10:20

Re: Docket No. 98P-0623/CP1

Dear Mr. Levin:

This letter is written in response to your July 24, 1998, citizen petition, docket number 98P-0623/CP1, alleging that there is no valid evidence to substantiate pre-amendment commercial distribution or marketing of the TSRH pedicle spinal screw system (K932029) because a number of the affidavits offered by Sofamor Danek in support of K932029 were false and misleading. You requested that the Food and Drug Administration revoke its decision that the TSRH pedicle spinal screw system is substantially equivalent to a preamendment device, and revoke all subsequent decisions based on that initial clearance. You requested, in the alternative, that the FDA institute an investigation to determine whether Sofamor Danek submitted false, fraudulent, or misleading information in support of its 510(k) notification, or that FDA refer the issue to the U.S. Attorney for the Eastern District of Pennsylvania, for prosecution.

Your allegations that Sofamor Danek submitted false and misleading affidavits in K932029 were forwarded, via FDA's Office of Regulatory Affairs, to FDA's Office of Criminal Investigations (OCI) for investigation. The initiation of this investigation thus satisfied one of the requests made in your petition. At the same time, I directed a review of the administrative file of K932029 to determine the impact of your allegations on the clearance for K932029.

As you requested, OCI investigated the matter, and referred its findings to the Department of Justice. The Department of Justice reviewed the findings and declined to prosecute the case. Accordingly, OCI regards the investigation as closed.

We have completed our review of OCI's investigation and the administrative file for K932029 and have determined that the questions concerning the affidavits identified in your citizen petition do not affect the final preamendment decision made by the agency because the investigation did not confirm wrongdoing in any affidavit critical to the decision. Therefore, the agency's clearance of Sofamor Danek's pedicle screws was proper and there is no basis to revoke K932029.

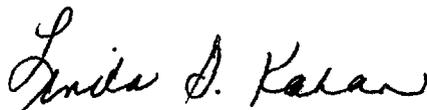
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PDN1

Criteria for establishing preamendment status are described in the Center for Devices and Radiological Health's (CDRH) guidance, Documentation Required For Preamendment Status. This document states that, in order to qualify for preamendment status, information must be presented that demonstrates a device was labeled, promoted, and distributed for a specific intended use (other than research or investigational use), and introduced or delivered for introduction into interstate commerce for that use prior to May 28, 1976.

The administrative file for K932029 documents that Dr. Harrington designed at least three different sizes of pedicle screws prior to May 28, 1976. As early as November 1966, Dr. Harrington forwarded his designs to Zimmer Manufacturing Company, Warsaw, Indiana, which in turn manufactured and shipped the screws to Dr. Harrington for use in his practice in Houston, Texas. During the agency's review of K932029, questions were raised regarding whether the devices used by Dr. Harrington were for clinical use or part of his orthopedic research. An affidavit submitted by a colleague of Dr. Harrington, as well as copies of journal articles, document that pedicle screws were clinically used by Dr. Harrington as part of his clinical practice to treat severe spondylolisthesis (Grades 3 and 4) of the fifth lumbar - first sacral (L5-S1) vertebral joint. This documentation meets the criteria for preamendment status established by the agency, and supports the preamendment claims made by Sofamor Danek in K932029. Therefore, the agency is denying your request to revoke the finding of substantial equivalence for K932029, and is further denying your request to revoke all subsequent decisions based on that clearance.

Sincerely yours,



Linda S. Kahan  
Deputy Director for  
Regulations and Policy  
Center for Devices and  
Radiological Health