



Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

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Mr. Arnold Levin
Levin, Fishbein, Sedran, & Berman
510 Walnut Street
Suite 500
Philadelphia, PA 19106

Re: Docket No.: 98P-0623

Dear Mr. Levin,

This is in response to your November 9, 2000, petition for reconsideration of our October 31, 2000, letter to you in which we denied your petition to revoke our finding of substantial equivalence for K932029. Your petition appears to be based on your belief that the administrative record does not demonstrate that the pedicle screws designed by Dr. Harrington were commercially distributed. In addition, you appear to believe that the devices were custom devices. For the reasons discussed below, we disagree with both of these assertions. Consequently, we are denying your petition.

Under § 10.33(d) of the Food and Drug Administration's (FDA) administrative practices and procedures regulations (21 CFR 10.33(d)), before granting a petition for reconsideration, FDA must determine that all of the following are true:

1. The petition demonstrates that relevant information or views contained in the administrative record were not previously or not adequately considered.
2. The petitioner's position is not frivolous and is being pursued in good faith.
3. The petitioner has demonstrated sound public policy grounds supporting reconsideration.
4. Reconsideration is not outweighed by public health or other public interests.

For the reasons discussed below, FDA believes that you have not met this burden. You have not demonstrated that FDA did not adequately consider the views and information contained in the administrative record. Nor have you shown that there are sound public policy grounds supporting reconsideration.

The administrative record establishes that Dr. Harrington placed his pedicle screws in commercial distribution prior to May 28, 1976. The letters of November 21, 1966, and February 16, 1967, from Dr. Harrington to Zimmer, along with the March 3, 1993 affidavit from

98P0623

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Dr. Dickson, establish that Dr. Harrington designed the screws and received them in interstate commerce. These documents also confirm that the screws were intended for use in the pedicle of the spine. The screws were designed by Dr. Harrington, and manufactured by Zimmer, solely for use in Dr. Harrington's practice. Consequently, under Title 21 CFR, Part 801.109, the screws could be shipped from Zimmer to Dr. Harrington without further labeling. The Harrington letters and the Dickson affidavit also make it clear that Dr. Harrington used these screws for clinical use and not as part of any research or investigation. In addition to the letters and the affidavit, the commercial use of these screws is further supported by journal articles documenting that Dr. Harrington used the screws prior to May 28, 1976.

Your letter implies that the screws used by Dr. Harrington were custom devices and, therefore, not in commercial distribution. We disagree. The custom device provision in section 520(b) of the Act was established on May 28, 1976, as part of the Medical Device Amendments. When Dr. Harrington used his screws, the concept of a custom device, as defined in the Act, did not exist. Notwithstanding this, the fact that something is a custom device does not mean that it is not in commercial distribution. The custom device provision exempts a device only from the requirements of sections 514 (performance standards) and 515 (premarket approval) of the Act. A custom device is subject to all other applicable provisions of the Act and may be in commercial distribution.

In summary, we reaffirm our position as stated in our letter of October 31, 2000, and deny your petition for reconsideration.

Sincerely yours,



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