



Atlanta District Office
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Atlanta, GA 30309

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September 16, 2003

VIA FEDERAL EXPRESS

William H. Longfield, President & CEO
C. R. Bard, Inc.
730 Central Avenue
Murray Hill, NJ 07974

Warning Letter
(03-ATL-26)

Dear Mr. Longfield:

During an inspection of your firm located at 8195 Industrial Blvd., NE, Covington, GA on 6/2-12/2003, Investigators Claudette D. Brooks, Patricia F. Hudson, and Chateryl Washington of the Food and Drug Administration's Atlanta District Office determined that your firm is a specification developer and distributor of the Tigertail™ Flexible Tip Ureteral Catheter and the 10 Fr Dual Lumen Ureteral Catheter. These products are devices as defined by Section 201(h) of the Federal Food, Drug and Cosmetic Act (the Act), 21 U.S.C. § 321(h). As a specification developer and distributor of these devices, you are responsible for ensuring their compliance with premarket requirements under the Act. See 21 C.F.R. 807.3(d)(3); 807.20; 807.81; Sections 301(a), 501(f)(1)(B) of the Act.

Our review of information collected during this inspection revealed a serious regulatory problem with these devices. Our investigators determined that while you obtained marketing clearance for the Bard Flexi-Tip Ureteral Catheter (premarket notification number K950300), your firm did not market this product. Instead your firm made significant changes to the [REDACTED] of the device cleared under this 510(k) premarket notification and introduced the Tigertail™ Flexible Tip Ureteral Catheter and the 10 Fr Dual Lumen Ureteral Catheter without the benefit of new 510(k)s. As described below, these [REDACTED] changes to your cleared device could significantly affect the safety or effectiveness of the device, and thus require the submission of a new premarket notification under 21 CFR 807.81(a)(3)(i).

Because of these changes, the Tigertail™ Flexible Tip Ureteral Catheter and the 10 Fr Dual Lumen Ureteral Catheter are misbranded under section 502(o) of the Act in that notices or other information respecting the modifications to the devices were not provided to the FDA as required by section 510(k) of the Act and 21 CFR 807.81(a)(3)(i). Because you did not file a new 510(k) premarket notification with FDA and receive a new determination of substantial equivalence for these devices, your devices are also adulterated under section 501(f)(1)(B) of the Act, in that they are Class III devices under Section 513(f) and do not have approved applications for premarket approval in effect pursuant to Section 515(a) or approved applications for an investigational device exemption under Section 520(g). (For a product requiring premarket approval before marketing, the notification required by section 510(k) of the Act is deemed to be satisfied when a premarket approval application (PMA) is pending before the agency. 21 CFR 807.81(b).)

The Tigertail Catheter that you market differs in several respects from the Flexi-Tip Catheter cleared for marketing under premarket notification number K950300. The cleared device had a shaft made of [REDACTED] and a tip of [REDACTED], both containing

[REDACTED] as a radiopaque agent. After an intermediate change to a shaft and tip of [REDACTED] both with [REDACTED] the Tigertail Catheter as currently marketed is apparently made of [REDACTED], with [REDACTED] as the radiopaque agent for the shaft, but [REDACTED] as the radiopaque agent for the tip.

Your own records indicate that you were aware that the change in [REDACTED] in the Tigertail Catheter necessitated a determination as to whether a new 510(k) would be required, under 21 CFR 807.81(a)(3)(i). In making this assessment, you attempted to follow the recommendations of FDA's guidance document regarding when to submit a new 510(k) for a change in a legally marketed device. This guidance indicates that a change in material formulation within the same generic material type is likely to be one that could significantly affect the safety or effectiveness of the device, triggering the need for a new 510(k) under 21 CFR 807.81(a)(3)(i), unless the proposed material formulation is identical to that used in another device legally marketed by your firm that has similar tissue contact and the proposed material does not alter the performance specifications of the device. Based on your documentation of your rationale for not submitting a new 510(k) for the Tigertail Catheter, FDA concludes that neither of these conditions were true, and that the material changes in fact could significantly affect the safety or effectiveness of your device.

First, your documentation indicates that you considered changes in [REDACTED] for both the shaft and tip materials and changes in [REDACTED] for the tip material separately from the changes in [REDACTED]. Since the [REDACTED] and [REDACTED] are inseparable from the [REDACTED], however, these agents should have been considered in conjunction with the [REDACTED] when comparing material formulations between the Tigertail Catheter and the [REDACTED] identified by Bard as a legally marketed device made of an identical material. Your records indicate that the Tigertail Catheter is constructed of [REDACTED] with [REDACTED] (shaft) and [REDACTED] with [REDACTED] tip), while the [REDACTED] is constructed of [REDACTED] with [REDACTED] with [REDACTED] (no mention of colorant). Consequently, the material used in the [REDACTED] device is not the same as that used in the Tigertail device. Because these materials are different, the comparison explained in your files does not support the conclusion that the change in materials in the Tigertail Catheter could not significantly affect the safety or effectiveness of the Tigertail Catheter. Instead, the change in materials leaves open questions about the biocompatibility of the device, and thus requires a new 510(k) to supply information to indicate that these changes have not had a negative effect on the safety or effectiveness of the device.¹

Second, your records also indicate that the [REDACTED] used in the Tigertail shaft and tip has [REDACTED] than the material used in the cleared Flexi-Tip Ureteral Catheter. This change to a [REDACTED] material could decrease the strength of the device, thereby impacting its performance specifications. This is another reason Bard should have concluded that the change in materials used in the Tigertail Catheter required a new 510(k).

In addition to the Tigertail Catheter, you market the 10 Fr Dual Lumen Ureteral Catheter, which is also based on the clearance of the Flexi-Tip Catheter (K950300). The 10 Fr Dual Lumen Ureteral Catheter differs from the 510(k)-cleared Flexi-Tip device in several respects, including a change in material from [REDACTED] to [REDACTED] (colorant and radiopaque agent not specified). While your documentation supports your conclusion that other changes to the device do not

¹ Your files regarding the earlier change from the cleared formulation to the [REDACTED] described above also fail to identify a legally marketed device constructed of the identical [REDACTED] formulation, and thus do not clearly support your conclusion that no 510(k) was required for this earlier material change. This change too may thus be one that could significantly affect the safety or effectiveness of the device. If you are still marketing a catheter using the [REDACTED] materials, it may also be misbranded and adulterated for the same reasons that the current Tigertail Catheter is misbranded and adulterated.

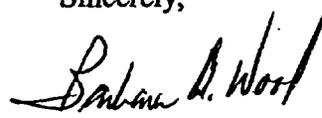
trigger the need for a new 510(k), FDA does not agree with your conclusion that the change in materials could not significantly affect the safety or effectiveness of the device because this is based on comparison to the material of the Tigertail Catheter, which was improperly introduced to the market without a new 510(k), as described above. These changes in material could significantly affect the safety or effectiveness of the device, in particular its biocompatibility.

You should take prompt action to correct these deviations. Failure to take prompt action may result in regulatory action being initiated by the FDA without further notice. These actions include, but are not limited to, actions for seizure, injunction and/or civil money penalties. Federal agencies are advised of the issuance of all warning letters about devices so that they may take this information into account when considering the award of contracts.

Please notify this office, in writing, within fifteen (15) working days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time within which the corrections will be completed.

If you have any questions concerning this letter, please call Serene N. Ackall, Compliance Officer at 404-253-1296. Your response should be sent to Serene N. Ackall at the address noted in the letterhead.

Sincerely,


for Mary Woleske,
Director
Atlanta District

Cc: Mary S. Mayo, Staff Vice President
C. R. Bard, Inc., Urological Division
Quality Assurance, Urological and Surgical Group
8195 Industrial Blvd.
Covington, GA 30014