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CERTIFIED MAIL
RETURN RECEIPT REQUESTED

Food and Drug Administration
Detroit District
1560 East Jefferson Avenue
Detroit, MI 48207-3179
Telephone: 313-226-6260

June 8, 2001

WARNING LETTER
2001-DT-19

Dane A. Miller
President and Chief Executive Officer
Biomet, Inc.
P.O. Box 587
Warsaw, Indiana 46581-0587

Dear Mr. Miller:

An inspection of your subsidiary firm, [REDACTED] [hereinafter [REDACTED] located in [REDACTED] was conducted on January 22-26, 2001 as a follow-up to your recall of the [REDACTED] Disposable Infusion Pump Kit. We note that [REDACTED] [hereinafter [REDACTED] is another of your subsidiary firms. The focus of the inspection at [REDACTED] was to determine where your firm's quality systems failed in allowing the release of adulterated product. The inspection found that your firm is operating in serious violation of the Federal Food, Drug, and Cosmetic Act (the Act), in that the methods used in, or the facilities or controls used for manufacturing, packing, storage or installation are not in compliance with the Quality System Regulation [Title 21, Code of Federal Regulations, Part 820]. These violations cause the [REDACTED] Disposable Infusion Pump Kit, Delivery Rate 2 ml/hr, to be adulterated within the meaning of Section 501(h) of the Act, as follows:

1. Failure to establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met, as required by 21 CFR 820.30(a). For example, the design activities conducted at [REDACTED] [REDACTED] were limited to developing production and processing procedures. [REDACTED] stipulated to [REDACTED] that the device was composed of off-the-shelf components and that the only decision remaining was to select the catalog number that provided the [REDACTED] ml/hr flow rate. In addition, SOP -04, Design Control, Revision 3, dated 5/16/00, from [REDACTED] Quality Manual, explained that design planning [REDACTED] is minimal in that the design for the device is provided by the customer and the customer's quote serves as the design plan. In view of the above, it was stated that [REDACTED] concluded that the design plan had been completed. There was no documentation available to describe the overall design and development planning process for the infusion pump kit.

2. Failure to establish and maintain procedures to confirm that the design output meets the design input requirements, as required by 21 CFR 820.30(f). For example, since the flow restrictor assembly component could not be purchased in finished form, it was designed and manufactured by [REDACTED]. There is no documentation to show that the interaction of the tolerances for the inside and outside diameters of the components used in the flow restrictor assembly was evaluated to assure an adequate seal around the flow restrictor tube.
3. Failure to establish and maintain procedures for validating the device design to ensure that the devices conform to defined user needs and intended uses, and include testing of production units under actual and simulated use conditions, as required by 21 CFR 820.30(g). For example, there is no documentation to show that the device was validated using the worst case scenario for "tolerance stack ups."
4. Failure to establish and maintain an organizational structure adequate to ensure that devices are designed and produced in accordance with the requirements of the Quality System Regulation, as required by 21 CFR 820.20(b). Specifically,
 - (a) 21 CFR 820.20(b)(1) requires you to establish the appropriate responsibility, authority, and interrelation of all personnel who manage, perform, and assess work affecting quality, and provide the independence and authority necessary to perform these tasks. We note that the individual acting as Quality Control Manager during our inspection also holds the position of Engineering Manager, and in that capacity he has been involved in product and process design, product testing, review of quality problems, and conducting periodic quality audits at the firm. These facts, as well as the number and type of other Quality Systems deviations documented during this inspection, have led us to conclude that you are in violation of 21 CFR 820.20(b)(1).
 - (b) 21 CFR 820.20(b)(2) requires you to provide adequate resources, including the assignment of trained personnel, for management, performance of work, and assessment activities, including internal quality audits, to meet the requirements of the Quality System Regulation. We have concluded, based on the facts outlined in point 5(a) above, that you are in violation of 21 CFR 820.20(b)(2).
5. Failure to establish adequate procedures for quality audits and to conduct such audits to assure that the quality system is in compliance with the established quality system requirements and to determine the effectiveness of the quality

system, as demonstrated by the number and type of deviations documented during this inspection, and as required by 21 CFR 820.22.

6. Failure to establish and maintain adequate procedures for the acceptance of incoming products, as required by 21 CFR 820.80(a) and (b). For example;
 - a) The incoming inspection procedure for the flow restrictor for the [REDACTED] Disposable Infusion Pump Kit was not validated to ensure that the required tests could be performed and, when the undated procedure for measuring the inside diameter of the restrictor was attempted in November 2000, it could not be performed. The decision to remove the requirement to measure the inside diameter of incoming flow restrictors was made in November 2000 based on a statement that flow restrictor assemblies are 100% flow tested, and that the flow test would catch any out of specification parts.
 - b) The revision of the inspection procedure [IP0063, Flow Accuracy Test], to include the requirement for the 100% inspection of flow restrictor assemblies was not approved until January 14, 2001.
 - c) There is no documentation of the performance of 100% inspection of flow restrictor assemblies for the [REDACTED] flow restrictor assemblies manufactured and distributed between May 2000 and December 2000.
7. Failure to document the evaluation, investigation and/or disposition of non-conforming product, as required by 21 CFR 820.90. For example, Nonconformance report 00-027 is dated 10/17/00 documents flow restrictor lot M15242 as being out of specification at the air flow test. At the time of the inspection, this nonconformance report had not yet been closed out.
8. Failure to establish and maintain adequate procedures to ensure that device history records are maintained to demonstrate that the device is manufactured in accordance with the device master record and the requirements of the Quality System Regulation, as required by 21 CFR 820.184. For example, the Production Router for [REDACTED] Lot # M15267, dated 11/9-22/00, does not document the results of the Inspect Flow Restrictor Assembly test or the final disposition of this lot. The Inspection Data Sheets for testing this lot showed [REDACTED] units were tested with [REDACTED] failing on the high side. Retesting of these [REDACTED] units reported [REDACTED] failed high and [REDACTED] failed low.

The above is not intended to be an all-inclusive list of deficiencies at [REDACTED]. It is your responsibility to assure adherence to each requirement of Quality

System Regulation. Other Federal agencies are advised of the issuance of all Warning Letters about medical devices so that they may take this information into account when considering the award of contracts. Additionally, pending 510(k) or PMA applications and export approval requests may not be approved until the above violations are corrected.

We request that you take prompt action to correct these violations and to ensure that your device manufacturing operations are in full compliance with the Act and regulations promulgated thereunder. Failure to promptly correct these violations may result in enforcement action being initiated by the Food and Drug Administration without further notice, such as seizure and/or injunction.

Please notify this office in writing, within fifteen (15) working days of your receipt of this letter, of any steps you have taken, or intend to take, to bring your firm into compliance. Also, please include an explanation of the steps being taken by Biomet to identify and prevent the recurrence of these or similar violations in the future. If corrective actions cannot be completed within 15 working days, please state the reason for the delay and the time frame within which the corrections will be implemented.

We realize that Biomet has multiple locations and many subsidiary corporations that are performing device manufacturing operations, and that you may contract out similar activities to others. We are very concerned about the compliance status of all of your locations based on the weaknesses in your quality systems demonstrated by the above inspectional findings. This letter is an official notification that FDA expects Biomet and all of its subsidiaries to be in compliance. We recommend that you evaluate all of your facilities and that corrective actions be taken corporate-wide if deficiencies are found. We further recommend that Biomet establish a system for ensuring corporate-wide compliance with the Act. We would welcome a meeting with you to discuss any actions you might be taking in this regard.

Your response should be directed to Melvin O. Robinson, Compliance Officer, at the above address.

Sincerely,



David M. Kaszubski
Acting District Director
Detroit District