



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

CERTIFIED MAIL  
RETURN RECEIPT REQUESTED

May 11, 1999

WARNING LETTER  
99-DT-08

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

- John W. Brown  
President & Chief Executive Officer  
Stryker Corporation  
2725 Fairfield Road  
Kalamazoo, Michigan 49001

Dear Mr. Brown:

An inspection of Stryker Corporation - Medical Division, 6300 Sprinkle Road, Kalamazoo, Michigan 49001 was conducted February 11 through 18, 1999 by Investigator William D. Tingley. Among other products, this inspection covered Secure 3000 beds, which are devices as defined by section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act). The inspection revealed that this device is misbranded within the meaning of Section 502(t)(2) of the Act in that you have failed to furnish a Report of Correction or Removal, as required by Title 21, Code of Federal Regulations (CFR), Part 806, promulgated under Section 519(f) of the Act.

Specifically, during this inspection the investigator was informed that your firm had identified problems with the head and foot side rail assemblies on all Secure 3000 beds manufactured between May 1995 and October 1996. The investigator was provided a copy of a technical bulletin issued on August 7, 1998 to Stryker field representatives. The technical bulletin identified the following problems with the Secure beds:

There is a potential for the side rail hoops on all Secure 3000 beds manufactured from May 1995 through October 1996 to become loose on the side rail support weldment. Screws used during this time period had a #10-24 thread and were screwed into a pem nut on the support weldment. In addition, it was found that the bosses on the inside panel would break off when attempting to remove a (loose) side rail panel.

The August 7, 1998 technical bulletin indicated that the solution to the loose side rails was to install 1/4 - 20 threaded screws into locking type weldnuts on the support weldments. The bulletin also required the use of BLUE LOCTITE 242 and hand tools as part of the correction. These changes were made in October 1996, but there is no indication that the users or service personnel were notified. Your firm issued the technical bulletin dated August 7, 1998 after receipt of three Medical Device Reports concerning loose or missing screws.

The problems described in the August 7, 1998 technical bulletin meet the definition of a correction as defined in 21 CFR, Part 806.1(d). This correction is reportable under 21 CFR Part 806(a) because it was initiated to "remedy a violation of the Act caused by the device which may present a risk to health." A risk to health includes situations where "the use of, or exposure to, the product may cause temporary or medically reversible adverse health consequences, or an outcome where the probability of serious adverse health consequences is remote."

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Kalamazoo, MI 49001

Since improperly functioning hospital bed side rails can, and have, caused serious adverse health consequences, the correction described in your firm's technical bulletin should have been reported to FDA within 10 working days after the correction was initiated.

This letter is not intended to be an all inclusive review of your firm's compliance status. It is your responsibility to ensure that all products marketed by your firm are in compliance with the Act and its implementing regulations. We recommend that you review your records and immediately report any unreported correction or removal actions.

We request that you take prompt action to correct this violation. Failure to promptly correct violations may result in enforcement action being initiated by the Food and Drug Administration without further notice. The Federal Food, Drug, and Cosmetic Act provides for the seizure of illegal products, the assessment of civil money penalties, and for injunction against the manufacturer and/or distributor of illegal products.

Please notify this office in writing within fifteen (15) working days of your receipt of this letter as to the specific steps you have taken to correct the stated violation. You should also include an explanation of each step being taken to identify and make corrections to assure that similar violations will not recur. If corrective action cannot be completed within 15 working days, state the reason for the delay and the time frame within which the corrections will be implemented.

Your reply should be directed to Sandra Williams, Compliance Officer, at the above address.

Sincerely,

  
for Raymond V. Mlecko  
District Director

cc via certified mail: Ronald Elenbaas, President, Stryker Corporation, Medical/Surgical Group.