



Food and Drug Administration
2098 Gaither Road
Rockville, Maryland 20850

APR 2 2001

WARNING LETTER

VIA FEDERAL EXPRESS

Mr. Helmut D. Link, President
Waldemar Link GmbH & Co.
Barkhausenweg 10
D-22339 Hamburg, Germany

Dear Mr. Link:

We are writing to you because on February 5-8, 2001, an investigator from the Food and Drug Administration (FDA) collected information that revealed serious regulatory problems involving your various prostheses for joint replacement including hips, knees, elbows, shoulders, fingers, toes, total femur, and fixation plates, screws, and staples.

Under a United States Federal law, the Federal Food, Drug, and Cosmetic Act (the Act), these products are considered medical devices because they are used to diagnose or treat a medical condition or to affect the structure or function of the body (Section 201(h) of the Act).

The above stated inspection revealed that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation of these devices are not in conformance with the Quality System regulation, as specified in Title 21, Code of Federal Regulations (CFR), Part 820. In legal terms, the products are adulterated within the meaning of section 501(h) of the Act, as follows:

- 1. Failure to establish and maintain procedures for implementing corrective and preventive action, as required by 21 CFR 820.100(a).** For example, procedures for CAPA are in draft stage. In addition, a review of 33 complaints dating from 6/99 revealed 2 complaints that indicated rust as a problem with the implantable devices. The products were returned to the vendor and replaced without appropriate review and follow-up.

2. **Failure to maintain procedures for the identification, documentation, review and approval of design changes before their implementation, as required by 21 CFR 820.30(i).** For example, a change was made to one of the devices and put into production before appropriate review and approval.
3. **Failure to establish and maintain procedures to ensure that formal documented reviews of the design results are planned and conducted at appropriate stages of the design development, as required by 21 CFR 820.30(e).** For example, there was no signed and dated review or approval for appropriately designated stages/phases of design controls for the new finger joint project.
4. **Failure to establish and maintain procedures for identifying valid statistical techniques, as required by 21 CFR 820.250(a).** For example, in-process testing and quality assurance final testing procedures have no statistical rationale.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA 483 issued at the closeout of the inspection may be symptomatic of serious problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective actions.

Given the serious nature of these violations of the Act, the various prostheses for joint replacement including hips, knees, shoulders, fingers, toes, total femur, and fixation plates, screws, and staples manufactured by Waldemar Link GmbH & CO., may be detained without physical examination upon entry into the United States (U.S.) until these violations are corrected.

In order to remove the devices from this detention, it will be necessary for you to provide a written response to the charges in this Warning Letter for our review. After we notify you that all responses appear to be adequate, we will request an establishment re-inspection at that time. As soon as the re-inspection has taken place, the implementation of your corrections has been verified, and you are notified that your corrections are adequate, your devices may resume entry into this country.

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Please notify this office in writing, within 15 working days of receipt of this letter of the specific steps you have taken to correct the noted violations. Include an explanation of each step being taken to identify and make corrections to any underlying systems problems necessary to assure that similar violations will not recur. Please include any and all documentation to show that adequate correction has been achieved. All documentation should be in English. In the case of future corrections, an estimated date of completion, and documentation showing plans for correction, should be included with your response to this letter. Please address your response to:

Edgardo Santiago, Chief
Orthopedic, Physical Medicine &
Anesthesiology Devices Branch
Office of Compliance
Division of Enforcement III (HFZ-343)
Center for Devices and Radiological Health
2098 Gaither Rd.
Rockville, MD 20850
USA

If you have any questions about the contents of this letter, please contact Ms. Brenda Hayden at the above address or at (301) 594-4659, ext. 150, or fax (301) 594-4672. You may obtain general information about all of FDA's requirements for manufacturers of medical devices by contacting our Division of Small Manufacturers Assistance at (301) 443-6597, or through the Internet at <http://www.fda.gov>.

Sincerely yours,



Larry D. Spears
Acting Director
Office of Compliance
Center for Devices and
Radiological Health

Cc: President
Link® Orthopaedics
339 Changebridge Road
Pine Brook, NJ 07058

Prepared: BHayden: 3/23/01
Revised: E Santiago: 3/26/01
Revised: KStutsman: 3/29/01
Initialed: GRodriguez: CLF 3/30

Bcc:

HFA-224
HFC-135
HFC-240
HFI-35 (purged)
HFZ-300
HFZ-306
HFZ-330
HFR- CE150 Matthew Sienko
HFR-CE1
HFZ-343 (firm file)
HFZ-343 Hayden
HFZ-343 E Santiago
HFZ-340 Stutsman
HFZ-340(4)

FEI: 3002808472

Last Date of Inspection: February 5-8, 2001

OC Receipt Date: March 9, 2001

Compliance Status: Not Acceptable.

OC Track: 86480