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**IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF DELAWARE**

UNITED STATES OF AMERICA, :
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 Plaintiff, :
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 v. : Criminal Action No. 07- **128M-JJF**
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 NUMED, INC. and ALLEN J. TOWER, SR., :
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 Defendants. :

INFORMATION

The United States Attorney for the District of Delaware charges that:

GENERAL ALLEGATIONS

At all times material hereto, unless otherwise alleged:

The Defendants

1. The defendant, NuMED, Inc. (NuMED), is a corporation located in Hopkinton, New York. NuMED was engaged in the manufacture and sale of medical devices, including interventional balloons, catheters, balloon delivery systems, and stents, primarily for the pediatric interventional cardiology market.

2. The defendant, Allen J. Tower (Tower), was the president and sole owner of NuMED. Tower directed, participated in, and controlled the manufacture and sale of the medical devices NuMED manufactured and sold.

Defendants' Medical Devices

3. From 1997 through 2004, NuMED and Tower, the defendants, developed



and manufactured the “Cheatham Platinum Stent” (hereinafter, the “CP Stent”), a device which was used to create, expand or hold open cardiac and other vessels.

4. From 1997 through November 2004, NuMED and Tower, the defendants, developed and manufactured a balloon-in-balloon catheter (hereinafter “BIB catheter”) primarily as a stent deployment device. The CP Stent was regularly sold pre-mounted on the BIB catheter.

5. The CP Stent and the BIB catheter were medical devices within the meaning of the Federal Food, Drug and Cosmetic Act (“FDCA”) in that each was an instrument or apparatus “intended for use in the cure, mitigation, or treatment of disease” in human beings or “intended to affect the structure or any function of the body” of human beings. 21 U.S.C. § 321(h)(2) and (3).

FDA Regulation of Medical Devices

6. The U.S. Food & Drug Administration (“FDA”) was the agency responsible for protecting the health and safety of the American public by ensuring, among other things, that medical devices designed for use in humans are safe and effective for their intended uses and are labeled accurately and in compliance with the law.

7. Defendants could not legally sell the CP Stent and/or the BIB catheter without first obtaining pre-market clearance and/or pre-market approval from the FDA, depending on the intended uses of the devices. The FDA could grant what is called a 510(k) pre-market clearance if it determined, following review of the data submitted in support of the applicant’s pre-market notification, that a device was substantially equivalent to a device (known as a predicate device) that was marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments to the FDCA. A device could only be found substantially

equivalent to a predicate device if, among other things, the intended use of the current device was the same as the intended use of a predicate device. If the intended use of the device was different from the intended use of a predicate device, substantial equivalence could not be found. Under such circumstances, the manufacturer could not legally market the device in interstate commerce unless the FDA had first reviewed and approved a pre-market application to market the device.

8. A device could be exempted from pre-market approval or clearance for several reasons. It could be exempted by an approved application for an investigational device exemption (IDE) pursuant to 21 U.S.C. § 360j(g). An IDE allows the shipment in interstate commerce of a device that is not approved or cleared, to permit clinical research. 21 U.S.C. § 360j(g). A device also could be exempted by an approved application for a humanitarian device exemption (HDE). 21 U.S.C. § 360j(m). An HDE allows the shipment in interstate commerce of a device that is not approved or cleared when: (a) the device is designed to treat or diagnose a disease that affects fewer than 4,000 individuals in the U.S.; (b) the device would not be available if the exemption was not granted; and (c) the benefits of the device outweigh its risks. 21 U.S.C. 360j(m)(2). In addition, a device could be exempted if it was a custom device, a device which is: (a) not generally available for purchase or for dispensing upon prescription; (b) not offered for commercial distribution; (c) specifically requested by a physician or dentist; (d) intended for use by an individual patient named in the order of the physician or dentist; and (e) made in a specific form for such individual patient. 21 U.S.C. § 360j(b). Furthermore, an unapproved device could be used in an emergency, if a physician informed the FDA that the device was necessary to correct an immediate, life threatening situation for which no approved device could be employed. 21 U.S.C. § 360bbb.

9. FDA categorized devices into three classes – Class I, Class II, and Class III - depending on the regulation necessary to ensure the safety and effectiveness of the devices for their intended uses. A device that was first introduced into commercial distribution after May 28, 1976, was, by operation of law, a Class III device. 21 U.S.C. § 360c(f)(1). A Class III device, unless it was exempt or the subject of a 510(k) pre-market clearance, required pre-market approval before it could be legally marketed in interstate commerce. 21 U.S.C. § 360e. Pre-market approval review by the FDA generally entailed, among other things, a review of clinical trials and safety data offered to confirm the safety and efficacy of the device as well as a review of the device’s labeling, which must include adequate directions for use.

10. A medical device is deemed “adulterated” under the FDCA if a person or company sells it to others for medical use before it is approved or cleared by the FDA. 21 U.S.C. § 351(f)(1)(B).

11. Each and every of these general allegations, as set forth in paragraphs 1-10, is incorporated into each and every count of this information.

SPECIFIC ALLEGATIONS

The CP Stent

12. In 1998, defendants NuMED and Tower first attempted to have the CP Stent granted a “Humanitarian Use Designation” (HUD). Obtaining a “HUD” designation is required before a sponsor can apply for permission to market an unapproved device under a humanitarian device exemption (HDE). The FDA rejected the application seeking a HUD designation for the CP Stent on December 22, 1998, because the application did not contain disease incidence

reporting for each indication and substantiating references for each indication and disease incidence.

13. On March 31, 2000, NuMED again applied for a HUD designation for the CP stent. On May 10, 2000, the FDA approved the HUD designation for the CP Stent for treatment of native and/or recurrent coarctation of the aorta (a congenital heart defect in which the aorta narrows or is obstructed distal to the left subclavian artery) in infants and children. Following that approval, on June 12, 2000, NuMED filed an application for an HDE for the CP Stent. The HDE designation would allow the CP Stent to be marketed in interstate commerce for coarctation of the aorta in infants and children as allowed under Title 21 U.S.C. § 360j(m).

14. On July 14, 2000, the FDA notified NuMED that the application was incomplete and requested a significant amount of additional material. NuMED provided some additional data over a range of dates in 2000, and the FDA recommenced its review of the application on or about November 9, 2000.

15. On January 23, 2001, at the conclusion of the review, the FDA issued a “major deficiency letter” that essentially stated that the FDA could not make a determination as to the safety of the device without a significant amount of additional clinical investigation data. In a conference call between the FDA and the defendants and others on March 16, 2001, the deficiencies and safety concerns arising from NuMED’s HDE application were discussed. The FDA told the defendants that more detailed clinical data was required and that it would be more appropriate to seek such data through the use of an “Investigational Device Exemption” (IDE) application. The FDA gave the defendants a number of options, among which was the

opportunity to withdraw the HDE and submit an IDE application under which it could legally conduct additional studies. NuMED subsequently withdrew its HDE on March 21, 2001.

16. To assist in preparing the IDE application for the CP Stent, NuMED hired an outside regulatory affairs contractor. The contractor discovered that NuMED had shipped approximately 309 CP stents to various physicians throughout the United States and strongly encouraged NuMED to notify the FDA about this.

17. On May 13, 2003, NuMED notified the FDA that the firm had been marketing the device in the U.S. as “a custom device.” This was the first indication the FDA had received that NuMED had been marketing the stent in the U.S.

18. On June 17, 2003, the FDA met with the defendants and told the defendants that the CP stent was not “a custom device” and that legal action could be taken against the firm and individuals within the firm. Tower agreed to stop distributing the CP Stent in the U.S. The FDA then instructed the defendants to recall all of the bare CP Stents that had been distributed. However, the FDA allowed the defendants to leave the covered CP stents in hospital inventories as an emergency “bail-out” device or for use in “compassionate use” cases pre-approved by the FDA. The FDA allowed this because they were informed by the defendant and others that there was no other device on the market that could be used to correct a certain type of congenital heart defect. Recalling the covered stents meant possibly depriving a cardiac surgeon of the use of the device as an emergency “bail-out” device in an operation originally intended to correct the defect by means of another procedure. At the conclusion of the meeting, the FDA believed that NuMED would not enter any more CP Stents into interstate commerce without an approved, case-specific, “compassionate use” exemption.

19. On August 5, 2003, the FDA received NuMED's IDE application seeking approval to place the CP Stent in interstate commerce for the sole purpose of conducting clinical trials for the treatment of coarctation of the aorta as allowed under 21 U.S.C. § 360j(g). The FDA disapproved the application and sent a major deficiency letter to NuMED on September 3, 2003, advising NuMED that it could not begin its clinical investigation and that it must recall all of the "covered" CP stents the FDA had previously allowed to remain at hospitals as bail-out devices and describing the application's deficiencies in detail.

20. On October 9, 2003, in partial response to the deficiency letter, NuMED submitted "copies of all case reports, consent forms and any follow-up that NuMED has on file at their facility." The FDA responded on October 29, 2003, and expressed concern that NuMED was having difficulty identifying the universe of patients treated with the CP stents. It ordered the firm to conduct a third-party audit of all patients treated in the U.S. At this time, FDA also ordered a center-directed FDA inspection of NuMED.

21. The FDA also questioned NuMED's distribution of the CP Stent overseas, given the definition of "interstate commerce" in the FDCA as "commerce between any state or territory and any place outside thereof." 21 U.S.C. § 321(b)(1). In order for NuMED to ship the CP Stent from New York to any overseas location the firm would have to have an export certificate issued by the FDA in accordance with Title 21 U.S.C. §§ 381 or 382. The FDA's database showed that NuMED had applied for an export certificate for the CP Stent on November 5, 2002, but the FDA had denied that application based on concerns about the device's safety and lack of data showing that earlier design deficiencies had been corrected. The FDA had notified NuMED on December 6, 2002, that the export certificate was denied.

22. On April 8, 2004, the FDA completed the inspection of NuMED that the FDA had ordered on October 29, 2003. As a result of the inspection, the FDA learned that NuMED moved the production of the CP Stent from its “R&D” division to its regular production division (both in New York) on January 3, 2000. Since that time, the firm had manufactured 3,101 CP Stents, though some of the larger batches were manufactured for testing purposes and were not distributed as medical devices. A listing of all CP stents shipped from NuMED’s New York facility showed that prior to January 1, 2000, the firm shipped 252 CP Stents and since that time had shipped another 2,623 CP Stents to physicians, hospitals, other medical device firms and wholesalers. Thus, the defendants manufactured and shipped approximately 2,855 CP Stents that were neither approved or cleared. Of that number, a total of 20 CP Stents were shipped under FDA approved “compassionate use” or “emergency use” provisions.

The BIB Catheter

23. In an article written by J.P.C., a doctor who assisted in the development of the BIB catheter, the author explained that the reason for the development of the BIB catheter was to “improve the efficacy and safety of stent deployment.” The purpose of the inner balloon was to allow for “repositioning of the stent before final deployment, when the outer balloon is inflated.”

24. In their internal documents and in literature prepared for their distributors, the defendants described the BIB catheter as a stent delivery device. Furthermore, the defendants routinely sold BIB catheters with CP Stents pre-mounted on them. The defendants had no prior catheters, or predicate devices, approved for use in stent deployment.

25. In October 2000, the defendants submitted a 510(k) application for a BIB

Percutaneous Transluminal Angioplasty (PTA) Catheter in which the defendants represented that the intended use of the catheter was “Percutaneous Transluminal Angioplasty (PTA) of the femoral, iliac and renal arteries. These catheters are not designed to be used in the coronary arteries.” The application did not list the deployment of stents as an intended use. In fact, the application had only one reference to stents: the Instructions for Use stated, “Do not attempt to purge balloons or crimp stents onto the balloon without a guidewire through the catheter lumen.”

26. After reviewing the application, the FDA directed the defendants to either remove the references to the stent or provide additional data concerning the compatibility between the stent and the catheter, including clinical trial results. The FDA further questioned why two balloons were necessary to do what one balloon had traditionally done.

27. The defendants submitted their response to the FDA’s request for additional information on February 28, 2001. Therein, the defendants deleted the reference to crimping stents on the BIB catheter in the Instructions for Use. The defendants also provided a revised intended use; the device’s intended use was now “for Percutaneous Transluminal Angioplasty (PTA) of the pulmonary valve...” There was no reference to the catheter being used as a stent deployment device in the revised intended use statement.

28. Following the defendants’ 510(k) submission for the BIB Catheter on October 3, 2000, the FDA advised the defendants on October 4, 2000, January 20, 2001, March 2, 2001, May 30, 2001, June 22, 2001, and on September 20, 2001, that the company could not market the BIB catheter.

29. After failing to respond to the FDA’s requests for additional information, the

FDA notified the defendants that it considered the 510(k) application for the BIB catheter withdrawn on December 31, 2002.

30. The defendants marketed the BIB catheter both domestically and overseas from on or about October 28, 1998, through November 4, 2004. During that period, the defendants sold approximately 5,223 BIB catheters - that were neither approved nor cleared by the FDA - domestically to 146 different customers.

31. Each and every one of these specific allegations, as set forth in paragraphs 12-30, is incorporated into each and every count of this Information.

COUNT ONE

32. From in or around August 1998, to on or about January 24, 2004, within the District of Delaware and elsewhere, NuMED, Inc. and Allen J. Tower, defendants herein, introduced and delivered and caused to be introduced and delivered for introduction into interstate commerce, including to the Alfred I. duPont Hospital for Children in Wilmington, Delaware, CP Stents, medical devices which were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B), in that the CP Stents did not have pre-market approval, as required by 21 U.S.C. § 360e, all in violation of 21 U.S.C. §§ 331(a) and 333(a)(1).

COUNT TWO

33. From in or around October 1998, to on or about January 24, 2004, within the District of Delaware and elsewhere, NuMED, Inc. and Allen J. Tower, defendants herein, introduced and delivered and caused to be introduced and delivered for introduction into interstate commerce, including to the Alfred I. duPont Hospital for Children in Wilmington, Delaware, BIB catheters, medical devices which were adulterated within the meaning of 21

Dated this _____ day of _____, 20____
I, _____, being duly sworn, depose and swear that the information
contained herein is true and correct to the best of my knowledge and belief,
and that I am not a party to this case.
Subscribed and sworn to before me on _____ day of _____, 20____
at _____, Delaware.
Notary Public for the State of Delaware
CNSL