IN THE UNITED STATES DISTRICT COURT

FOR THE EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	:	**CRIMINAL NO: 23-_____**
v.	:	**DATE FILED: _____**
PETER N. STOLL, III	:	
	:	**VIOLATION:**
	:	**21 U.S.C. §§ 331(a), 333(a)(2) (causing introduction of misbranded and**
	:	**adulterated medical devices into interstate commerce with the intent to**
	:	**defraud and mislead – 1 count)**

INFORMATION

COUNT ONE

THE UNITED STATES ATTORNEY CHARGES THAT:

At all times material to this information:

1. Company A was a company engaged in the manufacturing, packaging, marketing, sale, and interstate distribution of medical devices with its principal place of business located in Lehigh County within the Eastern District of Pennsylvania. Company A was a wholly-owned subsidiary and division of Company B, a global medical technology company headquartered in Melsungen, Germany.

2. From in and about March 2017 through in or about June 2017, Company A manufactured, marketed, packaged, sold, and distributed a surgical instrument called the ELAN-4 Electro Drill ("ELAN-4") to customers throughout the United States. The ELAN-4 was intended for cutting, sawing, and drilling of bone during surgical procedures.

3. From in or about July 2017 through in or about August 2017, Company A also manufactured, marketed, packaged, sold, and distributed a sterilization container system called the SterilContainer JS Series ("SterilContainer") to customers throughout the United States. The SterilContainer was intended to enclose another medical device to be sterilized, allowing sterilization of the enclosed device, and to maintain sterility of the enclosed device until it was used in medical and surgical procedures.

4. From in or about July 2015 through in or about August 2017, defendant PETER N. STOLL, III was employed by Company A as a Regulatory Affairs Specialist.

Regulation of Medical Devices

5. The United States Food and Drug Administration ("FDA") is the federal agency charged with the responsibility of protecting the health and safety of the American public by enforcing the Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"). Among the primary purposes of the FDCA was to assure that Americans are only exposed to medical devices that are safe and effective for their intended uses. FDA's responsibilities under the FDCA included overseeing a comprehensive regulatory scheme governing the manufacture, labeling, and distribution of all medical devices shipped or received in interstate commerce.

6. Virtually all devices introduced or delivered for introduction into interstate commerce after May 28, 1976, are automatically classified as class III devices as a matter of law under the FDCA, 21 U.S.C. § 360c(f)(1), and with certain exceptions, have an approved application for premarket approval prior to marketing and distribution in the United States. 21 U.S.C. §§ 360c(f)(1), 360e(a).

7. Under the FDCA, a class III device is deemed to be adulterated if: (a) it was required to have in effect an approved application for premarket approval under 21 U.S.C.

§360e(a); (b) there was no FDA-approved application for premarket approval in effect; and (3) it was not exempt from premarket approval as an investigational device under 21 U.S.C. § 360j(g). 21 U.S.C. § 351(f)(1)(B).

8. The sponsor of a device could avoid this automatic statutory class III designation, and thereby avoid the premarket approval process, if it obtained an order from the FDA reclassifying the device into class I or II or obtained from the FDA a clearance that the device was "substantially equivalent" to a legally-marketed predicate device that did not require premarket approval (commonly known as a cleared 510(k) notification). 21 U.S.C. §§ 360c(f), 360e(a) and (b), 360(k).

9. A 510(k) notification was required to be submitted to FDA for any device that was: (a) being introduced into commercial distribution for the first time (21 C.F.R. § 807.81(a)(1)); or (b) was currently in commercial distribution but had a significant change or modification in its intended use (21 C.F.R. § 807.81(a)(3)(ii)).

10. A device was deemed to be misbranded under the FDCA if it was distributed in interstate commerce without first submitting a 510(k) notification to FDA. 21 U.S.C. § 352(o). The FDCA prohibited the introduction or delivery for introduction, or the causing of the introduction or delivery for introduction into interstate commerce of an adulterated or misbranded device. 21 U.S.C. §§ 331(a), 333(a).

The ELAN-4 and SterilContainer Devices

11. The ELAN-4 and SterilContainer were a medical "device" under the FDCA because, *inter alia,* the ELAN-4 and SterilContainer were intended for use in the cure, mitigation, treatment, or prevention of disease. 21 U.S.C. § 321(h) (defining "device" for FDCA purposes). Accordingly, Company A was required by the FDCA and its implementing

regulations to either obtain premarket approval or 510(k) clearance from FDA prior to introducing the ELAN-4 and SteriContainer into interstate commerce.

12. As a Regulatory Affairs Specialist for Company A, defendant PETER N. STOLL, III was responsible for transmitting and administering the 510(k) submissions to FDA in order to obtain 510(k) clearances for the company's medical devices. Defendant STOLL was instructed by his superiors at Company A to make the required 510(k) submission to FDA, seeking clearance from the agency to distribute the ELAN-4 and SterilContainer devices in interstate commerce. Defendant STOLL failed to make any such submissions.

13. Defendant PETER N. STOLL, III falsely told employees at Company A and Company B (*i.e.,* Company A's parent company in Germany) that he had made a 510(k) submission regarding the ELAN-4 and SterilContainer when in fact he had not done so. Defendant STOLL made these false statements intending to defraud and mislead others at Company A.

14. On or about January 10, 2017, defendant PETER N. STOLL, III falsely and fraudulently informed representatives at Company A and Company B that FDA had cleared the ELAN-4 thus allowing Company A lawfully to begin distributing the ELAN-4 despite defendant STOLL knowing that in fact FDA had not provided any such 510(k) clearance or premarket approval.

15. To support his false claim that the ELAN-4 had received 510(k) clearance from FDA, defendant PETER N. STOLL, III created and produced a counterfeit document, mimicking the official letterhead of FDA bearing a forged digital signature of an FDA official, that stated that the ELAN-4 had received 510(k) clearance from FDA. Defendant STOLL took

these steps intending to create the false impression among Company A officers and employees that the ELAN-4 could be lawfully distributed in interstate commerce.

16. Defendant PETER N. STOLL, III transmitted the counterfeit FDA letter by email to several employees at Company A and Company B, including senior management employees, and falsely stated that "[t]he ELAN 4 Air Motor System has been cleared for marketing by the FDA. … We received the substantial Equivalence determination on Monday, January 9th." Defendant STOLL placed the fraudulent letter in Company A's filing system for FDA inspectors which led an FDA inspector to believe that the FDA had cleared the ELAN-4 via 510(k) clearance.

17. Based on the false and fraudulent representations made by defendant PETER N. STOLL, III, Company A marketed, sold, and distributed the ELAN-4 in interstate commerce. From in or about March 2017 through in or about June 2017, defendant STOLL caused Company A to repeatedly introduce ELAN-4 devices into interstate commerce that were adulterated and misbranded. Company A received approximately $78,840 in revenue from the purchasers of the adulterated and misbranded ELAN-4 devices.

18. Defendant PETER N. STOLL, III likewise never submitted a 510(k) notification to FDA on behalf of Company A related to the SterilContainer device. Nevertheless, for approximately one year, defendant STOLL falsely and fraudulently told others at Company A and Company B that he had submitted a 510(k) notification to FDA on behalf of Company A seeking clearance to market the SterilContainer.

19. On or about May 4, 2017 defendant PETER N. STOLL, III transmitted an email to employees of Company A and Company B that falsely and fraudulently stated "the [Company A] SterilContainer S2 (JS Series) has been cleared for marketing by the FDA under

K162254." The FDA reference number or "'K' Number" that defendant STOLL identified in his email as being assigned to the SterilContainer had actually been assigned by FDA to an entirely unrelated medical device manufactured by a different firm.

20. To corroborate his false statements contained in his email, defendant PETER N. STOLL, III crafted and forged a counterfeit letter from an FDA representative that falsely stated that FDA had acknowledged and received Company A's SterilContainer 510(k) submission. Defendant STOLL fabricated this letter intending to deceive others at Company A into believing that he had fulfilled his assigned work assignments, successfully submitted a 510(k) notification, and had obtained FDA clearance for the SterilContainer device. In fact, the SterilContainer had neither obtained 510(k) clearance nor premarket approval from FDA.

21. Based on defendant PETER N. STOLL, III's false representations that SterilContainer had obtained 510(k) clearance from FDA, Company A marketed, sold, and distributed the SterilContainer device in interstate commerce. From in or about July 2017 through in or about August 2017, defendant STOLL caused Company A to repeatedly introduce SterilContainer devices into interstate commerce that were adulterated and misbranded. Company A received approximately $59,781 in revenue from the purchasers of the adulterated and misbranded SterilContainer devices.

22. From in or about March 2017 through in or about August 2017, in the Eastern District of Pennsylvania and elsewhere, defendant

PETER N. STOLL, III,

with the intent to defraud and mislead, caused the introduction into interstate commerce, and delivery for introduction into interstate commerce, medical devices that were adulterated within

the meaning of 21 U.S.C. § 351(f)(1)(B) and misbranded within the meaning of 21 U.S.C. § 352(o).

All in violation of Title 21, United States Code, Sections 331(a) and 333(a)(2).

JACQUELINE C. ROMERO
UNITED STATES ATTORNEY

/s/Amanda N. Liskamm
AMANDA N. LISKAMM
DIRECTOR, CONSUMER PROTECTION BRANCH
DEPARTMENT OF JUSTICE

*No.*_ _ _ _ _ _ _ _ _ _

UNITED STATES DISTRICT COURT

Eastern District of Pennsylvania

Criminal Division

THE UNITED STATES OF AMERICA

vs.

PETER N. STOLL, III

INFORMATION

21 U.S.C. §§ 331(a), 333(a)(2) (causing introduction of misbranded and adulterated medical devices into interstate commerce with the intent to defraud and mislead – 1 count)

A true bill.

_____
Foreperson

Filed in open court this _____day,
Of _____A.D. 20_____

_____
Clerk

Bail, $_____