UNITED STATES DISTRICT COURT
EASTERN DISTRICT OF PENNSYLVANIA

UNITED STATES OF AMERICA	**:**	
v.	**:**	**No. 06-cv-5267**
CUSTOM ULTRASONICS INC., a corporation, and FRANK J. WEBER, an individual	**:**	

ANSWER TO COMPLAINT AND AFFIRMATIVE DEFENSES

1. Jurisdiction and venue are admitted.

2. Denied as stated. Paragraphs 2, 2A, 2A(1) and (2), and 2B(1) and (2) appear to include an FDA cleared medical device manufactured by corporate defendant which is, to the best of Defendants' information and belief, outside the scope of the injunction sought in this action, the System 83 Plus endoscope washer-disinfector manufactured and distributed by Custom Ultrasonics for over 20 years. The System 83 Plus is a Class II device that received FDA marketing clearance pursuant to 21 USC 360(k) (K983017) and which does not require PMA approval pursuant to 21 USC 360e. This device and its disinfection protocol are widely recognized as the best on the market. Defendants believe they agreed with DOJ that this case concerns only the System 83Plus *Miniflex*, a new device which has not yet been determined to be a substantially equivalent Class II device predicated on the System 83 Plus device for processing smaller endoscopes. Pursuant to 21 USC 360(K) Defendants have submitted notice of intent to market the Miniflex. to FDA in 2005. As a matter of statutory operation the Miniflex is considered a

Class III device regardless of risk presented by the device until a substantial equivalence determination is made.Conclusions of law are denied.

3. Admitted.

4. Admitted only that Frank J. Weber is President and Chief Executive Officer of Custom Ultrasonics Inc. and is sued in his official capacity.

5. Denied as stated. This action concerns only the Miniflex device.

6. Admitted.

7. Denied as stating conclusions of law requiring no answer.

8. Admitted and Denied as stated. Admitted that 4 Miniflex units were shipped; however FDA informed Defendants the device could not be marketed until FDA cleared it for marketing pursuant to 21 USC 360(K). On receiving this information Defendants quickly and voluntarily recalled the devices.

9. Denied. Allegations in this paragraph are false. To Defendants' knowledge, its devices as manufactured have never been found to have caused or contributed to any patient injury or death. Further, the safety of products manufactured by Custom Ultrasonics has never been at issue. These allegations should be stricken.

10, 11, 12, 13, 14, 15, 16, 16, 17. Denied as stating conclusions of law requiring no answer. To the extent factual issues are raised they are denied. Defendants received only one warning letter, in August 2005, and have since been diligently working to satisfy every issue raised by FDA including supplying information to FDA on or about October 26, 2006, the same day Defendants were presented with a Consent Decree which they were required to sign before seeing the Complaint. Counsel have an agreement reached December 5, two weeks after a Consent Decree

was signed. Said Consent Decree does not admit any violations alleged in the Complaint but does not expressly reflect the December 5 agreement of counsel. The proposed Consent Decree is hereby withdrawn unless and until it is revised to limit its application to the new Miniflex device only. Defendants were allowed only limited negotiation before signing the decree, which was revised to provide for denial of liability rather than "admission" of liability in the original version. FDA is fully aware Defendants will comply with regulations without an injunction.

WHEREFORE, Defendants respectfully request that Plaintiff's suit for permanent injunction be DENIED, dismissed and overruled, and the parties bear their own costs.

AFFIRMATIVE DEFENSES

1. Defendants assert the defense of unclean hands, in that Plaintiff did not show them the Complaint before it was filed or before signing the proposed Consent Decree. The Complaint is overbroad and exaggerated. An injunction is not necessary. Further, FDA infers that safety of Defendants' products is at issue, when it is not an issue, to create a false impression of wrongdoing.
2. Defendants assert laches, waiver and/or estoppel defenses , in that FDA cleared the System 83 Plus in 1998, after considering it for 4 years, yet included System 83 Plus in this action based on alleged QSR issues, while the QSR provisions became effective in 1997 and were never raised before 2005. Further, the Complaint at paragraphs 13, 14, 15 and 16 infers that Defendants were in "continuing violation" regulations without basis.
3. The regulating agency, FDA, and Defendants have a common mission, i.e. product

safety and efficacy. Safety and efficacy of the System 83Plus have never been at issue. This case is concerned only with procedures. Defendants would not have signed the proposed Consent Decree without assurances it would only apply to the Miniflex, and reasonably relied on this understanding. When the Complaint was seen to cover the System 83Plus as well as the Miniflex, counsel was again assured the pleading would apply only to the Miniflex, and counsel did not raise this issue with the Court in its December 18 conference. Defendants rely on the quality and performance of its products, which have never been found to have caused or contributed to patient injury in 23 years, and meet or exceed industry standards. Industry standards are referenced in CGMP and in QSR, promulgated in 1997. No injunction is necessary for defendants to comply with QSR.

4. FDA recognized Defendants' System 83 Plus device as a predicate device in clearing the new "Reliance" washer- disinfector in 2006, made by a competitor. FDA should therefore be estopped from seeking to enjoin continuing production and sale of System 83 Plus. Miniflex should be considered for FDA marketing clearance without the unfair interference of an injunction.

WHEREFORE, Plaintiff's Complaint should be denied and dismissed, and Defendants should not be assessed Plaintiff's costs.

Respectfully submitted,

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