

June 26, 2001

PMA Document Mail Center (HFZ-401)
Food and Drug Administration - CDRH
9200 Corporate Blvd.
Rockville, MD 20850

Re: PMA

Dear Dr. Bazaral,

In response to your email requesting additional information regarding our PMA submission, I have enclosed the following materials:

1. A discussion of one of the physical principles of gas transport during HFOV and its relationship to the use of cuff deflation. This document also includes a discussion of the origins of cuff deflation use during HFOV and how it was implemented during the MOAT2 trial.
2. Because high frequency ventilation is not usually included in physician training programs and as a new technique, experienced intensivists would not normally have used it, SensorMedics has always provided advanced training for its users. These programs both in the US and Europe started with a neonatal program that has trained more than one thousand neonatologists, respiratory therapists and nurses in the use of the 3100A. Following the approval for sale of the 3100A for pediatrics, a similar course was developed and started for pediatric intensivists. That program was also extremely successful. If the 3100B is approved for sale in the US, a similar program will be started to train adult intensivists. A prototype of that program was used to train the investigators and their teams for the MOAT2 trial. A copy of the program outline is attached.

This response may be sent to the panel. If you have any further questions, please do not hesitate to contact me.

Sincerely,

Alex Stenzler
Vice President
Advanced Technologies