

March 12, 2012

To Whom It May Concern,

On March 9, 2012, the FDA announced approval of the Sientra, Inc. PMA for marketing silicone gel filled breast implants in the United States. The product is manufactured by Silimed, Ltd in an FDA audited facility located in Brazil. The medical grade silicone is supplied by Applied Silicone Corporation, which has supported Silimed since 1988.

The Sientra PMA application process began over 10 years ago. Unlike the other applicants for PMA, Silimed made a decision to use then new fluorosilicone barrier membrane and pure silicone gel technology that has better cohesivity, strength and crush resistance than the traditional products on the market between 1970 and the present. Extra time and effort was needed to prove the safety and efficacy of the improved technology, but we can be confident that the performance of Silimed implants met the high standards imposed by the FDA after a grueling decade long IDE/PMA process. Furthermore, testing demonstrates there is no equivalent high strength gel available in the United States.

The relationship between ASC/Silimed has always been more than just as a supplier/user of commodity silicone. Together over a 26 year period, we optimized material and processing and developed an extensive database including physical, chemical and biological testing, accelerated aging, chemical extract analysis, 2 year implantation bioassays and teratology studies. We supported our data with over 30 FDA Master Files plus over 15 Master File Amendments and Compendium Summaries. We collaborate constantly with technical and regulatory support to ensure our manufacturing systems are consistent with current international standards and GMP requirements for Class III IDE/PMA devices.

While ASC takes no credit for the perseverance and skill of the Silimed/Sientra team in executing clinical trials with product made from our materials, we do take great pride in knowing that we have supplied technical support and advanced material performance that met or exceeded their expectations and we thank them for their loyal support.

Sincerely,



R. Alastair Winn
President