ASC APPLIED SILICONE CORPORATION

270 Quail Court • Santa Paula, CA 93060 • U.S.A.
(805) 525-5657 • (805) 933-1675 Fax
www.appliedsilicone.com

March 7, 2012
Kimberley Harden
Regulatory Affairs Assistant
BioSil Limited
127/129 Deerdykes View
Westfield Industrial Estate
Cumbernauld, Scotland, G68 9HN

Re: Applied Silicone Corporation and the United States Food and Drug Administration (FDA)

Dear Ms. Harden,

Applied Silicone Corporation (ASC) manufactures medical grade silicone polymer systems which may be used in the manufacture of Class I, Class II and Class III medical devices.

ASC has provided formal submission to the FDA's Center of Devices and Radiological Health division for over 30 ASC products in order to support preclinical safety data submitted by medical devices manufacturers that use ASC materials in their products and devises. The submissions that ASC has provided to the FDA were designed in accordance with "Silicone Devices Affected by Withdrawal of Dow Corning Silastic Materials," published in July 1993, in 58 CFR 36207 and memorandum "Guidance for Manufacturers of Silicone Devices Affected by Withdrawal of Dow Corning Silastic Materials," supplied by the FDA on May 24, 1993.

Included in the formal submission to the FDA are documents that provide substantial information in all the areas of Applied Silicone's activities, such as our quality systems, facility, manufacturing procedure and controls, material formulations, and specifications, physical, chemical and biological testing related to silicone polymers.

ASC is not registered with the United States Food and Drug Administration (FDA) as a device manufacturer as we do not manufacture any medical devices.

Access to these master access files are allowed only by written authorization from Applied Silicone Corporation.

If you have any additional questions or concerns, please feel free to contact me

Respectfully yours,

Annabelle Cortez
Quality Assurance Manager