PREMARKET NOTIFICATION (510(k) SUMMARY

Pursuant to 21 CFR Part § 807.92, the following data are presented :

1. **Applicant:**

W. L. Gore & Associates, Inc.
3750 W. Kiltie Lane
Flagstaff, AZ   86002
Phone: 520 - 779 - 2771

Contact:

John W. Nicholson, Associate
Date of Preparation: 11/26/96

2. a) **Applicant Device:**   S.A.M. Facial Implant

   b) **Common Name:**   Facial Implant

   c) **Classification Name:**   Surgical Mesh

3. **Predicate Devices:**

Because the only change that will result from this submission's clearance is the contraindication change discussed above in the devices' labeling, the individual S.A.M. devices will serve as their own substantially equivalent predicate devices. No changes to the S.A.M. Facial Implant products will be implemented as a result of this submission's clearance.

4. **Device Description:**

The applicant GORE S.A.M. Facial Implant devices are constructed of expanded polytetrafluoroethylene (ePTFE) and, in select configurations, fluorinated ethylene propylene (FEP) also. These devices are indicated for a broad variety of facial plastic and reconstructive applications. Expanded PTFE is acknowledged as one of the most inert biomaterials available to surgeons and its clinical performance in facial surgery demonstrates an essentially benign native tissue response to the material. The staggering of the node and fibril structure of ePTFE determines the degree and celerity with which host tissue attachment occurs.

The labeling changes proposed will not expand the devices' indicated uses and, therefore, no new safety and effectiveness questions arise as a result of this submission's clearance.

5.   Intended Use:

The S.A.M. Facial Implant devices are intended to be used for facial plastic and reconstructive surgery. This intended use is identical to that already cleared for these devices.

6.   Technological Characteristics:

Because this Notification involves only a labeling change, there are no technological changes to the devices which are being implemented.