

JUN 19 1996

K961210

PREMARKET NOTIFICATION 510(k) SUMMARY

1. Submitter Information: W. L. Gore and Associates, Inc.  
3750 West Kiltie Lane  
Flagstaff, Arizona 86002-0900  
Phone: (520) 779-2771  
Contact: John W. Nicholson  
Summary Preparation Date: March 27, 1996
  
2. Device Trade Name: SAM<sup>®</sup> Facial Implant  
Device Common Name: Facial Augmentation Implant Material  
Device Classification Name: Surgical Mesh
  
3. Substantially Equivalent  
Predicate Devices: SAM Facial Implant  
Non-Reinforced SAM Facial Implant  
SAM Facial Implant with Introducer

Because the proposed manufacturing modification does not materially effect the devices, they serve as their own predicates.

4. Device Description:

The only change that this optional manufacturing modification proposes is the creation of one or more tunnels within the implanted prosthesis. These tunnels provide additional sites for native tissue attachment and also facilitate in the placement of the implantable prosthesis.

No new materials or technological characteristics are being introduced, the device's therapeutic effect is not altered and the proposed change to the manufacturing process has no deleterious effects on the safety or efficacy of the devices when they are used as intended. These devices will still continue to meet all product specifications established for the original devices.

5. Intended Use:

SAM Facial Implant materials are indicated for plastic and reconstructive surgery. No new intended uses or new indications will be implemented as a result of this submission's clearance.

6. Technological Characteristics:

The manufacturing processes which were cleared in the Non-Reinforced SAM Facial Implant submission are identical to those used to produce these devices. There are no technological characteristic changes related to the implanted device and it achieves its clinical function in the same manner. The intraprosthetic tunnels serve merely to provide additional sites for host tissue attachment and to facilitate in device placement.

7. Conclusion:

The devices produced by this optional manufacturing process have the same indications, the same contraindications and enlist the same technological characteristics to achieve their equivalent clinical functions as implants for plastic and reconstructive surgery. The histological evaluation presented in **Attachment 2** reveals that the proposed modification will allow the devices to perform at least as well as the original devices. The descriptive characteristics within this submission are precise enough to ensure that the devices produced by this optional process are substantially equivalent to the original devices.

®SAM is registered in the United States Patent & Trademark Office