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Premarket Notification Summary

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Applicant Device :
Trade Name: GORE Spherex Implant
Common Name: Eye Shphere Implant
Classification Name: Eye Shphere Implant

Predicate Devices:

For the purposes of determining substantial equivalence, GORE cites the following as predicate devices:

- SAM Reinforced Facial Implant
- Porex MEDPOR Biomaterial, Conical Volume Augmentation (CVA) Implant
- Porex MEDPOR Biomaterial, Preformed Craniofacial Implant

Applicant Device Description:

The GORE Spherex Implant is an expanded polytetrafluoroethylene (ePTFE) and fluorinated ethylene propylene (FEP) laminate which is intended to be used as a space-filling, corrective prosthesis for the anophthalmic socket. The open microstructure of the ePTFE material allows for host tissue ingrowth. The device is machined to create a smooth, spherical structure which is provided in a variety of sizes.

Intended Use:

The GORE Spherex Implant is intended to be used as a corrective prosthesis for the anophthalmic socket. This is the same intended use as the predicate Porex CVA implant.

Technological Characteristics:

The GORE Spherex Implant is constructed of the same raw materials, undergoes the same manufacturing processes and is subject to the same quality control evaluations as the predicate SAM Reinforced Facial Implant. The devices are configured for their specific applications whether for rhinoplasty, malarplasty, maxilloplasty, orbital reconstruction or as corrective implants for the anophthalmic socket; the only difference is in the shape of the device. Design, material composition and intended performance reveal that the applicant and this predicate device incorporate identical technological characteristics.

The POREX CVA Implant is configured for the same indication as the applicant device. They both create the same therapeutic effect and, though they are not constructed of identical materials, they fulfill their equivalent clinical functions by providing the physician with a synthetic, biocompatible corrective prosthesis. The applicant device components, ePTFE and FEP, have established a successful clinical history in facial plastic reconstruction individually and combined and their use as a corrective prosthesis for the anophthalmic socket poses no new questions regarding safety and efficacy.

Nonclinical Data:

The evaluation of the GORE Spherex Implant reveals that the use of this device as a corrective prosthesis for the anophthalmic socket did not demonstrate any abnormal effects. The biological response was very similar to the response elicited elsewhere in the face when the material has been used in other applications as a plastic and reconstructive prosthetic. The foreign-body tissue response is minimal and there is extensive cellular migration laterally, posteriorly and anteriorly into the material. Vascularization into the eyeball is evident with numerous capillaries within the device's interstices. The results of the nonclinical data reveal that the material functioned safely and effectively in this application.

Conclusion:

This submission demonstrates that the applicant device and predicate CVA Implant device have the same indication. The applicant device incorporates the identical technological characteristics as the predicate GORE device and the only difference with the predicate POREX device is in the selection of materials. The successful clinical history of the applicant's components, singly and in combination, and the positive nonclinical implant data reveal that no new safety and effectiveness questions are posed by the use of these materials in this application.