BioDOptix is regulated by the FDA under 21 CFR Part 1271 and Section 361 of the Public Health Service Act.

References:
What is BioDOptix®?
BioDOptix is a human amniotic tissue allograft processed using proprietary technology. Human amniotic tissues have been shown clinically and scientifically to support soft tissue repair. BioDOptix is derived from tissues acquired from living, healthy donors after full term pregnancy and a scheduled Caesarean section. These tissues have been minimally processed and preserved to maintain the properties of the amniotic tissues. The product is only available through a physician or licensed healthcare provider.

What is an Allograft?
An allograft is tissue from a human donor that is transplanted from one body to another.

Why Human Amniotic tissues?
Clinicians have used human amniotic tissues for over a century as a biologic dressing in a broad range of therapeutic applications. They have been generally recognized as versatile wound coverings, with published clinical results cited extensively in the literature. Human amniotic tissues are an abundant source of collagen, as well as other proteins and cytokines. Human amniotic tissues are “immune-privileged” and therefore rarely cause an immune response in the human body.

Applications
BioDOptix is an amniotic-derived allograft used as a wound covering in the treatment of localized tissue voids and defects. Your physician can determine if your medical condition is appropriate for treatment with BioDOptix and, if so, will advise you as to the recommended treatment based on her professional assessment of your condition.

Common Clinical Applications of Amniotic Tissues
- Persistent Corneal Defects
- Corneal Ulcers
- Pterygium Surgeries
- Conjunctival Surface Reconstruction
- Bullous Keratopathy
- Chemical/Thermal Burns
- Ocular Surface Reconstruction
- Stevens Johnson Syndrome (SJS)
- Cicatricial Entropion
- Leaking Blebs post Glaucoma Surgery

BioD’s Commitment to Regenerative Science
BioDOptix is processed and distributed by BioDLogics, LLC, a company engaged in the development of advanced biologic products derived from human amniotic tissues obtained following caesarean births. Our research and development efforts are focused on the regenerative potential of birth tissues, given their unique biologic characteristics. We believe the use of living, healthy donors is a better approach to regenerative medicine.

Safety & Quality Are Our Highest Priorities.
BioD is committed to the safety of our patients and the quality of our products. BioD products are processed in accordance with the standards and regulations set forth by the Food and Drug Administration (FDA) and American Association of Tissue Banks (AATB) for tissue products. Our processes have been developed to preserve the amniotic tissues’ characteristics, including the extracellular matrix and cytokines, with a view to providing clinically beneficial products that benefit patients.

BioDOptix is derived from human amniotic tissues obtained from living, healthy and consenting mothers that are prescreened during pregnancy and selected based on our stringent donor suitability criteria.

Are There Risks Associated With the Use of BioDOptix®?
BioDOptix is an allograft that contains tissues derived from a living, healthy donor. As with the implantation of any human tissue, there is always the possibility of an allergic reaction or transmission of a communicable disease in connection with the use of this product. Consult your health care provider regarding adverse reactions or any questions you may have regarding the use of this product.