K950806

510(k) SUMMARY OF SAFETY AND EFFECTIVENESS INFORMATION

Solid Silicone and Silicone Sponge Implants

JUN - 5 1995

1. APPLICANT

MIRA, Inc.
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Date of Summary Preparation: February 21, 1995

2. DEVICE NAME

Proprietary Name: Solid Silicone and Silicone Sponge Implants
Common/Usual Name: Scleral Buckling Device
Classification Name: Extraocular Orbital Implants

3. PREDICATE DEVICE

MIRA, Inc. claims substantial equivalence of the Solid Silicone and Silicone Sponge Implants to currently marketed Solid Silicone (preamendment) and Silicone Sponge Implants (K780987A) manufactured and marketed by MIRA, Inc.

4. DEVICE DESCRIPTION

Solid Silicone and Silicone Sponge Implants are molded extruded silicone devices, available in a wide variety of shapes and sizes.

5. INTENDED USE

The intended use of the modified Solid Silicone and Silicone Sponge Implants is unchanged from the pre-amendment and cleared MIRA Solid Silicone and Silicone Sponge Implants. These devices are used to "buckle" the sclera in retinal reattachment surgery.

6. COMPARISON OF TECHNOLOGICAL CHARACTERISTICS OF THIS DEVICE TO THE PREDICATE

- Operational Principles

  The general operational principles are identical. Buckling implants are used to occupy space and provide compression for retinal reattachment. The change in materials has no impact on the function of these implants.

- Materials of Construction

  The only difference between the modified Solid Silicone and Silicone Sponge Implants is the silicone material. This difference is minor and does not affect safety or effectiveness.

- Models Available

  The models of Solid Silicone and Silicone Sponge Implants is unchanged.

- Sterility Status

  The Solid Silicone and Silicone Sponge Implants, like the currently marketed devices, are provided sterile.

7. TESTING

- Non-clinical Testing

  Non-clinical testing was performed to show that the new material used for the manufacture of MIRA Solid Silicone and Silicone Sponge Implants is not substantially

different from that of the original Dow Corning material. Physical testing was performed by the material supplier with results provided in FDA Master Files.

- Biocompatibility

There is no change in biocompatibility. Sterilized finished devices manufactured with new silicone material were tested for biocompatibility according to FDA "Tripartite Guidance" and according to "Table IV. Confirmatory Biological Testing" referenced in FDA "Guidance for Manufacturers of Silicone Devices Affected by Withdrawal of Dow Corning Silastic Materials. Testing demonstrated that the implants were non-toxic and biocompatible.