

MAY -2 1997



K970910

510(k) Summary

1.0 Date Prepared

March 6, 1997

2.0 Submitter (Contact)

David Timlin
Xomed Surgical Products
Jacksonville, FL
(904) 279-7532

3.0 Device Name

Proprietary Name: Xomed Silicone Block/Strip
Common Name(s): Silicone Block/Strip
Classification Name: ENT synthetic polymer material

4.0 Device Classification

ENT : Procure 77 Class II ; 21 CFR 874.3620 Tier 3
General and Restorative: Unclassified

5.0 Device Description

Xomed Silicone Block/Strip are sterile, implants produced from silicone elastomer molded into a squares and/or rectangular shapes of various sizes and thicknesses and durometer as specified on each product label.

6.0 Intended Use

The Silicone Blocks/Strips are intended for use as an implant material to aid in surgical repairs in various otorhinolaryngological surgical procedures and space occupying augmentation in reconstructive Head & Neck surgery.

7.0 Substantial Equivalence

Both silicone sheeting and silicone block were marketed by Xomed prior to May 16, 1976. A reinforced version of the Silicone Sheeting was introduced in 1995 via 510(k) [K953013]. The Silicone Block and Strip proposed in this submission are substantially equivalent to these predicate products in that they have the same intended use and are made from essentially the same base material. Additionally, the proposed devices are similar to predicate products from other manufacturers, i.e. Implantech Silicone Block (K913882), Dow Silicone Block and McGhan Silicone Block (510k unknown). Again, the intended use and base materials are essentially identical.

032