

K964484

510(k) Summary

1.0 Date Prepared

November 6, 1996

JAN 24 1997

2.0 Submitter (Contact)

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

3.0 Device Name

Proprietary Name: **Kartush TM Patcher**

Common Name: Tympanic Membrane (TM) patch

Classification Name: Not Classified

5.0 Device Classification

The Kartush TM Patcher has not yet been classified. It is similar to a number of current ENT devices: a tympanostomy tube, in that both are intended to be implanted in the tympanic membrane; a nasal septal button, in that both are intended to cover a perforation in mucosal lined tissue; and silicone sheeting, as both are silicone implant material for ENT repairs and both are used for patching TM perforations.

Tympanostomy Tube	Procode 77 ETD	Class II; 21CFR 874.3880	Tier 2
Nasal Septal Button	Procode 77 LFB	Class II;	Tier 1
Silicone sheeting	Procode 77 KHJ	Class II; 21 CFR 874.3620	Tier 2

6.0 Device Description

The Kartush TM Patcher is comprised of a double flange design, using silicone elastomer as the biocompatible material. The configuration is similar to a collar button style tympanostomy tube, with the exception that no through-hole or lumen is present. A variety of sizes or diameters of the TM Patcher will be available for approximating different size perforations. Alternately, the TM Patcher may be trimmed to size by the surgeon to fit the existing perforation. The flange thickness is the same as silicone sheeting currently used to treat TM perforations. The soft, pliable flange, which can conform to the surface of the TM, also easily folds for removal of the device as needed. As with nasal septal buttons, the silicone elastomer material is the same as used in the manufacture of Xomed tympanostomy tubes.

7.0 Intended Use

Kartush TM Patcher is intended for use as a patch to aid coverage of a tympanic membrane perforation in a dry ear.

8.0 Substantial Equivalence

The Kartush TM Patcher described in this notification has the same intended use as the currently used silicone sheeting. But silicone sheets, although commonly used, are not designed specifically for TM patching. The TM Patcher, designed and intended specifically for TM patching, draws on the design benefits of the other predicate devices, the tympanostomy tube and the nasal septal button, that have proven to be safe as a TM implant and effective as a nasal perforation patch, respectively. The TM patch functions in the same regard as the silicone sheeting, but the central shaft and inner flange of the TM Patcher provide added security to help reduce displacement. A more secure patch helps to restore the protection of the middle ear effected by the tympanic membrane. Although it is expected that there could be adverse effects similar to the predicate devices, such as infection, premature extrusion, widening or persistent perforation, or granulomatosis reaction; the TM Patcher does not raise any new issues of safety or effectiveness and certainly involves less risk than that associated with a surgical repair.