



K963727

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**510(k) Summary**  
**Hoffman Long-Term H/A Coated Ventilation Tube (with Liner)**

**1.0 Date Prepared**

September 5, 1996

**2.0 Submitter (Contact)**

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

**3.0 Device Name**

Proprietary Name: Hoffman H/A Coated Long-Term Ventilation Tube with Liner

Common Name: Long Term Vent Tube

Classification Name: Tympanostomy Tube

**5.0 Device Classification**

Tympanostomy Tube    Procode 77 ETD    Class II; 21CFR 874.3880    Tier 2

**6.0 Device Description**

The Xomed Hoffman H/A Coated Long-Term Ventilation Tube is comprised of two components, using three biocompatible materials. One component of the device is an outer titanium tube with a polished inner lumen. A Hydroxylapatite (H/A) coating covers a portion of the exterior surface of the outer tube where it is positioned against the bony wall of the ear canal when surgically placed. The second component is a removable inner tube made of fluoroplastic. This liner can be removed and replaced by the surgeon should occlusion of the liner lumen occur. The liner design precludes the internal migration of the polymer liner into the middle ear space.

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**7.0 Intended Use**

The Xomed Hoffman H/A Coated Long-Term Ventilation Tube with Liner is intended for prescription use only, as a means of communication of the outer and middle ear to provide long-term ventilation or drainage of the middle ear when inserted under the tympanic membrane.

**8.0 Substantial Equivalence**

The Hoffman H/A Coated Long-Term Ventilation Tube with Liner is substantially equivalent to other currently marketed long-term ventilation tubes in that it has the same intended use, the same materials and/or equivalent design characteristics as shown in the predicate device labeling. The substantially equivalent ventilation tubes are as follows:

Xomed Silverstein Permanent Aeration Tube (SPAT) [Xomed Surgical Products, Inc]	(Preamendment)
Jahn Hydroxylvent™ Tube w/ fluoroplastic liner [Smith & Nephew/Richards]	(K900267)
Fluoroplastic/Titanium Ventilation Tubes [Smith & Nephew/Richards]	(Unknown)