K964061

FEB 20 1997

PREMARKET NOTIFICATION SUMMARY

1. **Applicant :** W. L. Gore and Associates, Inc.
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2. **Applicant Device :** GORE EZE-Sit Angioscopic Valvulotome Kit

Common Name : Angioscopic valvulotome

Classification Name : Kit components have the following classification names:

Valvulotome
Angioscope
Intravascular administration set

3. **Predicate Device :**

For the purpose of determining substantial equivalence, GORE cites the following as predicate devices :

URESIL Valvulotome (marketed under contract as the "GORE EZE-Sit Valvulotome") - K 930011
CLARUS Angioscope - K 900894
NEURONAVIGATIONAL Angioscope - K 923996

NOTE: One of these two, or any other FDA-cleared, commercially marketed, angioscopes will be used in the angioscopic valvulotome kit.

GORE Irrigation System - Premarket notification submitted to General Hospital/Personal Use Division; number and clearance documentation to be supplemented to this submission upon receipt.

4. **Applicant Device Description :**

The angioscopic valvulotome kit, intended to be used for venous valve incision and intravascular tributary identification during vein preparation for in-situ bypass, consists of commercially available components cleared under previous and/or separate 510k premarket notifications: the GORE EZE-Sit Valvulotome, an angioscope, and an irrigation system. All kit components will be used within their labeled and FDA-cleared indications; the only difference is that GORE will write a single Instructions for Use document to facilitate surgical use.

5. **Intended Use :** The angioscopic valvulotome kit is intended to be used for venous valve incision and intravascular tributary identification during vein preparation for in-situ bypass.

6. **Technological Characteristics :**

As all components of the GORE EZE-Sit Angioscopic Valvulotome will be used within their labeled and FDA-cleared indications, with the only difference being that GORE will write a single Instructions for Use document to facilitate surgical use, there are no changes in technological characteristics. The applicant GORE kit and the predicate devices have the same intended uses, the same classifications, are reviewed by the same panels and utilize the same technological characteristics to achieve equivalent clinical results. No new safety and effectiveness questions arise when using the angioscopic valvulotome kit as intended.