

JAN 30 1997

K964041

X. Summary of Safety and Effectiveness

**Classification Name:** Accessories, Hemodialysis  
21 C.F.R. § 876.5820 (1994).

**Common/Usual Name:** Cutaneous Compression Device for Use in Hemodialysis.

**Proprietary Name:** At present, no proprietary name has been chosen for this device.

**Establishment Registration:** Mr. Robert R. Stevens has submitted an application for establishment registration in accordance with the requirements of 21 C.F.R. § 807.20 (1994). He has been assigned Owner/Operator Number 9020052.

**Classification:** Under Section 513 of the Federal Food, Drug, and Cosmetic Act, this device is classified into Class II.

**Performance Standards:** As of the date of this Premarket Notification submission, no Performance Standards have been established for this device under Section 514 of the Federal Food, Drug, and Cosmetic Act. As such, no actions have been taken to comply with Section 514 Performance Standards.

**Labeling:** Proposed labeling is included in this submission.

**Substantial Equivalence:** This device is substantially equivalent to the following legally-marketed devices ("Predicate Devices") in terms of safety, effectiveness, and intended use:  
**Product:** Cutaneous Compression Device for General Hospital Use  
**Manufacturer:** Concurrent Device Manufacturing, Inc.  
**510(k) Number:** K955270  
**Substantial Equivalence Date:** August 8, 1996

**Product:** Cutaneous Compression Device for Use in Hemodialysis  
**Manufacturer:** Concurrent Device Manufacturing, Inc.  
**510(k) Number:** K951973  
**Substantial Equivalence Date:** Determined to be Class I Exempt device under 21 C.F.R. § 876.5820, as evidenced by letter from Lillian Yin dated June 13, 1995.