

B K990041

510 (k) SUMMARY

This Summary was prepared in accordance with the Safe Medical Devices Act of 1990 and 21 CFR 807.92

I GENERAL INFORMATION

Establishment	Denco Inc. Wilmington, Delaware 19809 Phone (302) 798-4200 Fax (302) 798-1607
Contact Person	Dudley W. Spencer Ph.D.
Device Name	Total Containment Device TCD®
Classification Name	None

II PERFORMANCE STANDARDS

No mandatory standards have been established.

III SUBSTANTIAL EQUIVALENCE

This medical device is substantially equivalent to our currently marked device. TCD®.

IIII INDICATIONS FOR USE

For use making sterile connections of PVC tubing in blood processing applications.

IV TECHNOLOGICAL CHARACTERISTICS

Our marked TCD® was designed to make sterile connections with 4.0 mm O.D. PVC tubing in processing applications. Fluid is gently expressed as the tubing is bent and placed in a tube clamp for the welding process. The entrance to the clamp was designed for nominally sized 4.0 mm O.D. tubing.

This modification simply removes the "nub" at the clamp entrance, allowing the clamp to accept for loading either nominally sized 4.0 O.D. or 4.3 O.D. PVC tubing. Both sizes of tubing presents a 3.0 mm I.D. for the welding function of the blood flow pathway.