

BK000022

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 DE 19809 Phone (302) 798-4200 Fax (302) 798-1607
Contact Person	Dudley W. Spencer Ph.D.
Device Name	Total Containment Device Model B – 50
Classification Name	None

II PERFORMANCE STANDARDS

No mandatory standards have been established

III INDICATIONS FOR USE

This medical device is substantially equivalent to our currently marketed TCD Model B – 40.

IV TECHNOLOGICAL CHARACTERISTICS

Our Marketed TCD Model B – 40 is designed to make sterile connections with nominally sized 4.3 mm OD tubing.

This modification provides for a different clamp or Taper Lock to accommodate up to nominally sized 5.4 mm OD tubing.