


K. 510(k) statement according to 21 CFR §807.93

Device identification

Trade name: Transwaag Disk 01
Common name: Automated scale/mixer for blood collection
Classification Name: Device, Blood Mixing and Blood Weighing
(81 KSQ)
21 CFR § 864.9195
Class I

I certify in my capacity as General Manager of Sarstedt Inc., I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.


(Signature)

Peter Rumswinkel

January 31, 2003