

510(k) Notification for Fenwal Needle/Tube Sampling Protector
and Needle Safety Cover
December 10, 1991

SUMMARY OF SAFETY AND EFFECTIVENESS

DATE: December 10, 1991

SUBJECT: Needle/Tube Sampling Protector
Needle Safety Cover

MANUFACTURER: Fenwal Division
Baxter Healthcare Corporation
Rt. 120 and Wilson Road
Round Lake, IL 60073

The Fenwal Needle/Tube Sampling Protector (Code 4R5121) and a Needle Safety Cover (Code 4R5122) provide an added measure of safety for healthcare workers during blood sampling. These devices have a broad flange at the site of needle insertion, which protects the healthcare worker's hand from accidental needle sticks. This safety feature aids in the safe collection of vacuum tube samples and the disposal of donor needles after blood donations. During a U.S. field trial of the Needle/Tube Sampling Protector, no accidental needle sticks occurred during over 4400 uses of the device.