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K962671

AMERICAN BIOPRODUCTS COMPANY
Premarket 510(k) Notification
STA[®]-vWF Calibrator Kit

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VII. SAFETY AND EFFECTIVENESS SUMMARY

The STA[®]-vWF Calibrator is a citrated human plasma containing von Willebrand Factor (vWF) at the normal level, intended for use as a calibration plasma for the assay of vWF antigen by the immuno-turbidimetric method performed on the STA[®] analyzer (Diagnostica Stago, France; K942117).

Each manufactured lot of STA[®]-vWF Calibrator is assigned a vWF value which is determined with an internal vWF reference that has been assayed against the third International Standard 91/666 for Factor VIII and von Willebrand Factor established in 1992.

Each STA[®]-vWF Calibrator kit provides 6 x 1-ml vials of citrated human plasma in freeze-dried form. The vWF value of each lot is provided in the Assay Value insert supplied with each kit. The freeze-dried reagent in intact vials is stable for 24 months after the date of manufacture, when stored at 2°-8°C; the reconstituted plasma remains stable for 4 hours on board the STA[®] analyzer.