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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

Submitter Name and Address:	Baxter Healthcare Corporation Biotech Group, Fenwal Division Route 120 and Wilson Road Round Lake, IL 60073
Contact Person:	Steven B. Binion, Ph.D. (708) 270-4294
Date Summary Prepared:	February 22, 1994
Trade/Proprietary Name of Device:	Optipress™ Automated Blood Component Extractor
Common or Usual Name of Device:	Blood Component Extractor
Classification Name of Device:	Blood Bank Supplies (21 CFR 864.9050)
Predicate Device Under Which Substantial Equivalence Is Being Claimed:	Optipress™ Automated Blood Component Extractor cleared for market entry under 510(k) BK910032
Device Description:	The product provides for the semi-automated separation of centrifuged whole blood into blood components. The outflow of blood components from the container is accomplished by a pressure plate. The blood components are expressed from the bottom and/or top ports of the container depending on the program selected. An optical sensing system controls clamps on the outlet tubing and thereby maintains the cellular interface at the appropriate level.
Intended Use of Device:	Semi-automated separation of whole blood into blood components.
Comparison of Technological Characteristics of the Device vs. the Original Predicate Device:	The product has not been revised from the predicate device. A new indication for use has been added; Program B will allow for the semi-automatic separation of Platelet Rich Plasma (contained in Fenwal polyvinyl chloride plastic transfer packs) into Platelet Concentrates and Platelet Poor Plasma.

Brief Discussion of Tests and Their Results Submitted in the Application:	A clinical study in two centers has demonstrated that the Program B on the Optipress™ Extractor can be used in conjunction with polyvinyl chloride plastic transfer packs on either Optipac™ Units or conventional Blood-Pack® Units to produce Platelet Concentrates and Platelet Poor Plasma in a reproducible manner from centrifuged Platelet Rich Plasma. A total of 36 units of Platelet Concentrates were prepared in this manner. The platelet yield averaged 7.84×10^{10} platelets per unit with 89% of the units meeting the minimum FDA requirement of 5.5×10^{10} platelets per unit at outdate. Acceptable in vitro indices were found in all units after 5 days of storage.
Conclusions Drawn from the Nonclinical and Clinical Tests that Demonstrate that the Device is Safe, Effective, and Performs As Well As or Better than the Predicate Device:	Based on the data from the clinical study, it is concluded that Program B of the Optipress™ Extractor is acceptable for the production of Platelet Concentrates and Platelet Poor Plasma from Platelet Rich Plasma contained within Fenwal polyvinyl chloride transfer packs.