

8. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

BH030022

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Date Summary Prepared: 5 March 2003

Device Trade Name: Fresenius Compomat G4 and
Compomaster NT

Common Name: Blood component separator

Classification Name: Separator, semi-automated, blood
component

Substantial Equivalence: The device is substantially equivalent to
the Compomat G3 currently marketed.

Device Description: The Compomat G4 functions as an
automated press, clamp and sealer, and,
with the use of programs provided by the
Compomaster NT, records and stores
the information concerning the
manufacture of the components.

Intended Use: Compomat G4 is a semi-automated
blood component separator used for
blood component separation and
preparation.

Technological Characteristics: The proposed device has the same
technological characteristics and the
same basic design and configuration as
the predicate device.

Performance Data: A direct comparison of the Compomat
G4 to the Compomat G3 was performed
by the Red Cross Bloodbank Noord,
Netherlands. With regards to component
volumes, reduction of leukocyte content
of the erythrocyte concentrate, and
distribution of thrombocytes, the
Compomat G4 is equivalent to the
Compomat G3.