

B2040005

8.0 510(k) Summary of Safety and Effectiveness Information

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Device Trade Name: Fresenius CompoGuard and
Donationmaster NT

Common Name: Blood mixer

Classification Name: Device, Blood mixing and blood weighing

Substantial Equivalence: The device is substantially equivalent to
the Biomixer 330/323 and the
Composeal Mobilea currently marketed.

Device Description: The CompoGuard functions as a blood
mixing and weighing device, and, with
the use of programs provided by the
Donationmaster NT, records and stores
the information concerning the donation
procedure.

Intended Use: CompoGuard is used by trained
professionals in blood banks for blood
collection and data registration.

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

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