510(k) SUMMARY OF SAFETY AND EFFECTIVENESS

K964973

COMPANY NAME AND CONTACT PERSON

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DEVICE NAME	MODEL NUMBER
CAP VRF45 Cardiotomy/Venous Reservoir	CAP VRF45

NAME OF PREDICATE OR LEGALLY MARKETED DEVICE

Gish Cardiotomy/Autotransfusion/Pleural Drainage Venous Reservoir; K890504
Gish Cardiotomy/Venous Reservoir: K883923
Terumo CAPIOX SX; K922799

DESCRIPTION OF DEVICE

Consistent with the intended use described in K883923 and K890504, the Gish CAP VRF45 is a disposable device designed to be used in-line with an extracorporeal circuit during cardiopulmonary bypass surgery. The Gish CAP VRF45 Cardiotomy/Venous Reservoir is designed to be used in-line during cardiopulmonary bypass surgery as a storage reservoir for venous return blood and to filter and defoam intrathoracic suction blood. It is also to be used for collection and autotransfusion of postoperative shed blood.

The device consists of a two (2) chamber or compartment configuration. See Figure 1 for diagrams of the device which demonstrate the compartmental configuration and indicate all component material compositions.

The lower chamber of the reservoir is the venous return blood compartment. The compartment functions to receive venous return blood by means of a central channel. The blood subsequently passes through an outer filter screen (160 micron) before deposition in the reservoir.

The upper chamber of the reservoir is the intrathoracic suction blood compartment (cardiotomy). The compartment functions as a cardiotomy to receive blood recovered by intrathoracic suction. The blood subsequently passes through two (2) defoamer layers and two (2) filtration layers (20 - 28 micron and 160 micron) before deposition in the reservoir. The central core of the filter assembly of the upper chamber is virtually identical in design, function and material composition the Gish Cardiotomy Venous Reservoir (K883923) and the Gish Cardiotomy/ Chest Drainage System (CAP35DF, K874924). In addition, the composition is also of similar construction to the Gish Cardiotomy/Autotransfusion Reservoir (ATR: K870792). The Gish CAP VRF45 will be offered with or without the 20 - 28 micron filtration layer.

Consistent with the intended use described in K890504 and with other Gish reservoirs, specifically the Cardiotomy/Autotransfusion Reservoir (K870792) and Cardiotomy/Chest Drainage System (CAP35DF, K874924), the reservoir may be used postoperatively for collection and autotransfusion of the same patient's postoperative shed blood. Essentially, in the postoperative autotransfusion mode, the reservoir will function (just as in the operative mode) to collect, filter and defoam intrathoracic blood. In the autotransfusion mode, the blood is returned via the extracorporeal circuit to the same patient and essentially the reservoir (in conjunction with an appropriate manometer system (e.g. water or dry manometer)) functions in a chest drainage capacity.

STATEMENT OF INTENDED USE

The Gish CAP VRF45 is indicated for use during cardiopulmonary bypass surgery as a storage reservoir for venous return blood and to filter and defoam intrathoracic suctioned blood prior to its return to the extracorporeal circuit. The CAP VRF45 is indicated for the collection and autotransfusion of the same patient's postoperative shed blood.

STATEMENT OF INTENDED USE OF PREDICATE/MARKETED DEVICES

The Gish CAP-VR (K890504) is indicated for use during cardiopulmonary bypass surgery as a storage reservoir for venous return blood and to filter and defoam intrathoracic suction blood. Collection and autotransfusion of postoperative shed blood.

The Gish CVR (K883923) is indicated for use during cardiopulmonary bypass surgery as a storage reservoir for venous return blood and to filter and defoam intrathoracic suction blood.

The Terumo CAPIOX SX (K922799) reservoir is indicated for use during cardiopulmonary bypass surgery as a storage reservoir for venous return blood and to filter and defoam intrathoracic suction blood.

DETERMINATION OF SUBSTANTIAL EQUIVALENCE

This premarket notification submission provides substantial equivalence information and rationale which addresses the introduction to commercial distribution of the Gish CAP VRF45 Cardiotomy/Venous Reservoir. The Gish CAP VRF45 is substantially equivalent to other cardiotomy/venous reservoirs which are in commercial distribution These predicate/marketed devices include the Gish Cardiotomy/Venous Reservoir (K883923), the Gish Cardiotomy/Autotransfusion/Pleural Drainage Venous Reservoir (K890504) and the Terumo Medical Corporation CAPIOX SX (K922799, with the CAPIOX oxygenator).

The Gish CAP VRF45 has an intended use which is substantially equivalent to other cardiotomy/venous reservoirs which are in commercial distribution, such as the Gish Cardiotomy/Venous Reservoir, the Gish Cardiotomy/Autotransfusion/Pleural Drainage Reservoir and the Terumo Medical Corporation CAPIOX SX reservoir.

The Gish CAP VRF45 has technological characteristics which are substantially equivalent to the Gish Cardiotomy/Venous Reservoir, the Gish Cardiotomy/Autotransfusion/Pleural Drainage Reservoir and the Terumo CAPIOX SX reservoir. The design, construction, materials and nominal specifications of the Gish CAP VRF45 are either identical or substantially equivalent to the aforementioned reservoirs.

A Device Comparison Chart comparing the technological characteristics of the Gish CAP VRF45 with two substantially equivalent devices the Gish Cardiotomy/Venous Reservoir and the Gish Cardiotomy/Autotransfusion/Pleural Drainage Reservoir is provided in Appendix III.

In addition to the above assessment of intended use and technological characteristics, Gish Biomedical, Inc. has provided additional information to support substantial equivalence of the Gish CAP VRF45. This includes biocompatibility testing on sterilized product and in-vitro bench testing on sterilized and accelerated aged product. These data support that the Gish CAP VRF45 Cardiotomy/Venous Reservoir does not significantly affect safety and effectiveness and is substantially equivalent to other marketed cardiotomy/venous reservoirs.