5 510(K) SUMMARY

In accordance with 21 CFR 807.87(h) and 21 CFR 807.92, the 510(k) Summary is provided.

510(k) Summary

I. SUBMITTER

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II. DEVICE

Trade Name of Device:	Terumo Operational Medical Equipment Software (TOMEs), Version 7.1
Common or Usual Name:	Blood establishment computer software and accessories
Classification Name:	Blood establishment computer software and accessories
Regulatory Class:	Class II (Special Controls)
Product Code:	MMH

III. PREDICATE DEVICE

Table 1: Predicate Device Information

Device	Product Classification	Trade Name Of Predicate Device	Manufacturer and 510(k) Holder	510(k) Clearance Number
Predicate	MMH	Vista® Information System	Terumo BCT	BK150228

IV. DEVICE DESCRIPTION

A. Device Identification

Terumo Operational Medical Equipment Software (TOMEs) is a dedicated software that integrates standalone Terumo BCT transfusion devices into a single entity and allows for remote management via the customer's local area network (LAN).

B. Device Characteristics

The TOMEs system is a client-server application installed on personal computers running Microsoft® Windows®.

C. Device Description

Terumo Operational Medical Equipment Software (TOMEs) is software as a medical device (SaMD) installed on a server connected to the customer's LAN. Through the LAN connection, TOMEs is capable of connecting to and bi-directionally communicating with other supported devices (TSCD-II Sterile Tubing Welders (BK170098)), laboratory equipment (scales, barcode

readers) or to third-party Information Management Systems (IMS) (e.g., BECS, EMRs, LIMs) that are available on the customer's LAN. Once connected to the LAN, TOMEs allows the user to:

- Configure connected medical devices and laboratory equipment:
  - Adapt device and program settings for each connected device.
  - Enable defined workflow management of connected equipment.
  - Create stations to connect peripheral devices (TSCD-II welders, scales, barcode readers) with TOMEs.
  - Communicate with multiple devices in a consistent way.
- Centralize data management:
  - Exchange selected data between connected devices, equipment, and other information management systems.
  - Collect process data from each connected device.
  - Easily navigate through and search for process data.
  - Schedule export data in data formats such as XML, CSV, EXC, HL7, and TXT.
  - View and manage data from the IMS.
  - Import input data from external sources (such as other IMS and data files).
  - Link data from different sources in one general view.
  - Export PDF reports.

D. Environment of Use

TOMEs is intended for use in an environment associated with blood component collection and manufacture.

E. Materials of Use

TOMEs is a software solution; it does not explicitly include materials or hardware as part of the distributed product.

F. Key Performance Specifications/Characteristics of the Device

TOMEs is a software solution. Performance characteristics are influenced by feature utilization, operator ability, and implementation configuration. Detailed configuration and performance characteristics are available in the device labeling.

V. INTENDED USE

TOMEs (Terumo Operational Medical Equipment software) is software that enables defined workflow management of connected equipment to enforce user created algorithms that help facilitate donation management and the manufacture of blood components.

VI. TECHNOLOGICAL COMPARISON

The TOMEs system is technologically comparable to the predicate device, the Vista Information System, in that both devices are software solutions intended to be installed on the client-side hardware. Both systems are compatible with Windows operating systems and can be accessed via common web browsers. The hardware and software requirements to operate both systems are comparable and outlined in the substantial equivalence discussion of this 510(k) submission.

VII. PERFORMANCE DATA

The following performance data were provided in support of the substantial equivalence determination.

A. Mechanical Testing

N/A. Mechanical testing is not applicable to the TOMEs system, as it is a software only solution.

B. Biocompability Testing

N/A. Biocompatibility testing is not applicable to the TOMEs system, as it is a software only solution.

C. Electrical Safety and Electromagnetic Compatibility (EMC) Testing

N/A. Electrical safety and EMC testing is not applicable to the TOMEs system, as it is a software-only solution.

D. Software Verification and Validation Testing

Software verification and validation testing were conducted, and documentation was provided as recommended by FDA's Guidance for Industry and FDA Staff, "*Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices*." The software for this device was considered as a "major" level of concern because it qualifies as an accessory to a Blood Establishment Computer Software (BECS). Device and User requirements supporting the intended use were verified and validated as appropriate.

E. Sterility Testing

N/A. Sterility Testing is not applicable to the TOMEs system, as it is a software only solution.

F. Stability/Shelf Life Testing

N/A. Stability testing is not applicable to the TOMEs system, as it is a software only solution.

G. Clinical Studies

N/A. The functionality of TOMEs provides workflow, configuration, and data management for connected devices that does not alter the process already employed by Blood Establishments. Therefore, the TOMEs product does not require clinical studies.

VIII. CONCLUSIONS

The proposed device, TOMEs, Version 7.1, was developed in accordance with *IEC 62304:2006 Medical Device Software – Software life cycle processes*. The verification and validation data provided in this notification demonstrates that TOMEs, Version 7.1 is substantially equivalent with regard to the safety and efficacy of the predicate device, Vista Information System, Version 4.0.

TOMEs, Version 7.1 incorporates the same essential technology characteristics, operational principal as the predicate for each core design feature. Therefore, the TOMEs system, is at least equivalent to a legally marketed predicate with respect to intended use, essential technology, and bench performance.