510(k) Summary

In accordance with 21 CFR 807.87(h), a 510(k) summary is included that meets the conditions as outlined for a 510(k) summary in 21 CFR 807.92.

Submitter Information:

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Device:

Device Classification Name: Software, Blood Bank, Web Products

Trade Name: bexWISE API v1.0

Common Name: Blood Establishment Computer Software

Review Panel: Hematology

Classification Product Code: MMH

Device Classification Regulation: 21 CFR 864.9165

Device Class: Class II

Predicate Device:

510(k) Number	Predicate Trade Name	Manufacturer	Product Code
BK140091	DoVac Elite v2.0	IT Synergistics, LLC	MMH
BK140149	Donor-IDTM ver. 3.2.6	Healthcare-ID, Inc.	MMH

Device Description:

The bexWISE Application Programming Interface (API) is a software only Medical Device Accessory, streamlining the exchange of donor and donation-related data among 510(k) cleared Blood Establishment Computer Systems (BECS). This API includes a user-friendly graphical user interface (GUI) labeled as the "bexWISE API Portal," enabling users to monitor transferred data and identify any errors or warnings that might have occurred.

Intended Use/Indications for Use:

The bexWISE API (v1.0) is for use in blood establishments to facilitate communication between 510(k) cleared Blood Establishment Computer Systems (BECS), allowing the exchange of donor and donation-related data used to determine donor eligibility and donation suitability.

Non-Clinical Testing

IT Synergistics' activities to assure adherence to design control include determining new risks and analyzing those risks. Hazards are mitigated by identifying new requirements to reduce the hazard, providing appropriate errors or warnings to the user. Based on the identified hazards and requirements, test cases are written and executed to verify that all conditions identified to mitigate identified hazards have been implemented as stated by the requirements.

Clinical Testing:

Clinical performance testing is not applicable for the *bex*WISE API v1.0 as it is a software only device.

Conclusion:

The bexWISE API v1.0 was developed using design controls incorporated in IT Synergistics development processes. The non-clinical data supports the safety of the device and indicate that the software device will perform as well as the predicate device as demonstrated by supporting validation activities performed and verifies that the device performs as designed, per the functional requirements, when utilized within its intended use.