

**510(K) Summary
for
imEXPRESS™**

1. SPONSOR

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2. DEVICE NAME

Proprietary Name: imEXPRESS™
Common/Usual Name: Data Management Software
Classification Name: Software, blood-bank, stand-alone products

3. PREDICATE DEVICE

- IDM SURROUND System, version 3.0, (BK010028)

4. INTENDED USE

The imEXPRESS™ software application provides the physical connection, translation, and routing capability to enable clinical laboratory instruments to communicate interactively with laboratory information systems. In a blood bank or transfusion service setting, imEXPRESS™ provides an interface between laboratory information systems and laboratory instrumentation used for the analysis of donor blood samples. The imEXPRESS™ software does not control any of the instruments to which it is connected.

5. DEVICE DESCRIPTION

The intended use of the imEXPRESS™ software is the same as the intended use of the IDM SURROUND System. The proposed and predicate devices are both software applications can be used for the transfer of laboratory instrumentation data from donor or patient test samples. The IDM SURROUND System has information management enhancements that are not included in the proposed imEXPRESS™ software.

6. BASIS FOR SUBSTANTIAL EQUIVALENCE

The proposed and predicate devices are substantially equivalent based on similarities in technical characteristics. Both the proposed and predicate software devices receive information from laboratory instruments and allow the user to store and transfer the information. Data Innovations has prepared the necessary documentation for the imEXPRESS™ software to meet the required elements for a software-controlled device with a MINOR level of concern as outlined in FDA's "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices." Documentation to satisfy the requirements of "Reviewer Guidance for a Premarket Notification Submission for Blood Establishment Computer Software" has also been provided.