# SPECIAL 510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
# DECISION SUMMARY

## I Background Information:

### A 510(k) Number

K210127

### B Applicant

Beckman Coulter, Inc.

### C Proprietary and Established Names

iQ200 System
iChemVELOCITY Automated Urine Chemistry System

### D Regulatory Information

| Product Code(s) | Classification | Regulation Section | Panel |
|---|---|---|---|
| LKM | Class II | 21 CFR 864.5200 - Automated Cell Counter | HE - Hematology |
| KQO | Class I | 21 CFR 862.2900 - Automated urinalysis system | CH - Clinical Chemistry |
| GKL | Class II | 21 CFR 864.5200 - Automated cell counter | HE - Hematology |
| JIL | Class II | 21 CFR 862.1340 - Urinary glucose (nonquantitative) test system | CH - Clinical Chemistry |

## II Review Summary:

This Changes Being Effected (CBE) 510(k) submission contains information/data on modifications made to the submitter's own CLASS II device requiring 510(k). The following items are present and acceptable.

1. The name and 510(k) number of the SUBMITTER'S previously cleared device (K101852 and K022774).

2. Submitter's statement that the **INDICATIONS FOR USE/INTENDED USE** of the modified device as described in its labeling **HAS NOT CHANGED** along with the proposed labeling which includes instructions for use, package labeling, and, if available, advertisements or promotional materials (labeling changes are permitted as long as they do not affect the intended use).

3. A description of the device **MODIFICATION(S)**, including clearly labeled diagrams, engineering drawings, photographs, user's and/or service manuals in sufficient detail to demonstrate that the **FUNDAMENTAL SCIENTIFIC TECHNOLOGY** of the modified device **has not changed. This change was for a modification to the iQ200 System and the iChemVELOCITY Automated Urine Chemistry System software to be implemented as part of the corrective action for a field action initiated by BEC in Z-0913-2020 and Z-0914-2020, respectively as reported on April 15, 2020. The workstation software, known as Analysis Processor User Interface (APUI), was modified to flag duplicate specimens.**

4. Comparison Information (i.e., similarities and differences) to the submitter's legally marketed predicate device including, labeling, intended use, and physical characteristics.

5. A Design Control Activities Summary which includes:

    a) Identification of Risk Analysis method(s) used to assess the impact of the modification on the device and its components, and the results of the analysis.

    b) Based on the Risk Analysis, an identification of the verification and/or validation activities required, including methods or tests used and acceptance criteria to be applied.

The labeling for this modified subject device has been reviewed to verify that the indication/intended use for the device is unaffected by the modification. In addition, the submitter's description of the particular modification(s) and the comparative information between the modified and unmodified devices demonstrate that the fundamental scientific technology has not changed. The submitter has provided the design control information as specified in The New 510(k) Paradigm and on this basis, I recommend the device be determined substantially equivalent to the previously cleared (or their preamendment) device.