September 10, 2025

Beckman Coulter, Inc
Shilpa Pillai
Staff Regulatory Affairs Specialist
11800 S.W. 147th Avenue
Miami, Florida 33196

Re: K252580
Trade/Device Name: iQ200 System
Regulation Number: 21 CFR 864.5200
Regulation Name: Automated Cell Counter
Regulatory Class: Class II
Product Code: LKM, KQO
Dated: August 14, 2025
Received: August 15, 2025

Dear Shilpa Pillai:

We have reviewed your section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (the Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. Although this letter refers to your product as a device, please be aware that some cleared products may instead be combination products. The 510(k) Premarket Notification Database available at https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm identifies combination product submissions. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Additional information about changes that may require a new premarket notification are provided in the FDA guidance documents entitled "Deciding When to Submit a 510(k) for a Change to an Existing Device"

(https://www.fda.gov/media/99812/download) and "Deciding When to Submit a 510(k) for a Software Change to an Existing Device" (https://www.fda.gov/media/99785/download).

Your device is also subject to, among other requirements, the Quality System (QS) regulation (21 CFR Part 820), which includes, but is not limited to, 21 CFR 820.30, Design controls; 21 CFR 820.90, Nonconforming product; and 21 CFR 820.100, Corrective and preventive action. Please note that regardless of whether a change requires premarket review, the QS regulation requires device manufacturers to review and approve changes to device design and production (21 CFR 820.30 and 21 CFR 820.70) and document changes and approvals in the device master record (21 CFR 820.181).

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801 and Part 809); medical device reporting (reporting of medical device-related adverse events) (21 CFR Part 803) for devices or postmarketing safety reporting (21 CFR Part 4, Subpart B) for combination products (see https://www.fda.gov/combination-products/guidance-regulatory-information/postmarketing-safety-reporting-combination-products); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820) for devices or current good manufacturing practices (21 CFR Part 4, Subpart A) for combination products; and, if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR Parts 1000-1050.

All medical devices, including Class I and unclassified devices and combination product device constituent parts are required to be in compliance with the final Unique Device Identification System rule ("UDI Rule"). The UDI Rule requires, among other things, that a device bear a unique device identifier (UDI) on its label and package (21 CFR 801.20(a)) unless an exception or alternative applies (21 CFR 801.20(b)) and that the dates on the device label be formatted in accordance with 21 CFR 801.18. The UDI Rule (21 CFR 830.300(a) and 830.320(b)) also requires that certain information be submitted to the Global Unique Device Identification Database (GUDID) (21 CFR Part 830 Subpart E). For additional information on these requirements, please see the UDI System webpage at https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/unique-device-identification-system-udi-system.

Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to https://www.fda.gov/medical-devices/medical-device-safety/medical-device-reporting-mdr-how-report-medical-device-problems.

For comprehensive regulatory information about medical devices and radiation-emitting products, including information about labeling regulations, please see Device Advice (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance) and CDRH Learn (https://www.fda.gov/training-and-continuing-education/cdrh-learn). Additionally, you may contact the Division of Industry and Consumer Education (DICE) to ask a question about a specific regulatory topic. See the DICE website (https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/contact-us-division-industry-and-consumer-education-dice) for more information or contact DICE by email (DICE@fda.hhs.gov) or phone (1-800-638-2041 or 301-796-7100).

Sincerely,

Takeesha Taylor-bell -S

Takeesha Taylor-Bell
Deputy Director
Division of Immunology and Hematology Devices
OHT7: Office of In Vitro Diagnostics
Office of Product Evaluation and Quality
Center for Devices and Radiological Health

Enclosure

DEPARTMENT OF HEALTH AND HUMAN SERVICES
Food and Drug Administration

Indications for Use

Form Approved: OMB No. 0910-0120
Expiration Date: 07/31/2026
See PRA Statement below.

510(k) Number *(if known)*
K252580

Device Name
iQ200 System

Indications for Use *(Describe)*
The iQ200 System is an in-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel, and microscopic sediment analysis. Optionally, the iQ200 Analyzer can be used as a stand-alone unit, or the results from the iQ200 analyzer can be combined with other urine chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.

Type of Use *(Select one or both, as applicable)*

☒ Prescription Use (Part 21 CFR 801 Subpart D) ☐ Over-The-Counter Use (21 CFR 801 Subpart C)

CONTINUE ON A SEPARATE PAGE IF NEEDED.

510(k) Summary

This summary of safety and effectiveness information is submitted in accordance with 21 CFR § 807.92.

510(K) Number : K252580 Date Prepared: 27th August 2025

I CONTACT DETAILS

Company Name : Beckman Coulter, Inc
Address : 11800 S.W. 147th Avenue Miami IL 33196 United States
Telephone : (305) 380-3800
Contact : Ms. Shilpa Pillai
Contact Email : spillai@beckman.com

II. DEVICE NAME

Device Trade Name : iQ200 System
Common Name : Automated cell counter
Classification Name : Counter, Urine Particle
Regulation Number : 864.5200
Product Code(s) : LKM, KQO

III. LEGALLY MARKETED PREDICATE DEVICE

Predicate # K022774, K093861, K210127
Predicate Trade Name : iQ200 System
Product Code : LKM, KQO

IV. DEVICE DESCRIPTION SUMMARY

The iQ200 Series Automated Urine Microscopy system utilizes a specimen sandwiched between lamina layers presented to a microscope with a CCD video camera. This ensures the specimen is precisely within the microscope's focus and field of view. The system automates sample handling and analyte classification for improved data reporting and management. Specimens are aspirated by an autosampler, and individual particle images are isolated in each frame. The Auto-Particle Recognition (APR) software classifies images into 12 categories, and more, with 27 additional sub-classifications available. Particle concentration is determined by the number of images and the analyzed volume. Results are checked against user-defined criteria and sent for operator review or directly uploaded to the LIS. Specimen results can be edited, imported, and exported.

V. INTENDED USE/INDICATIONS FOR USE

The iQ200 System is an in-vitro diagnostic device used to automate the complete urinalysis profile, including urine test strip chemistry panel, and microscopic sediment analysis. Optionally, the iQ200 Analyzer can be used as a stand-alone unit, or the results from the iQ200 analyzer can be combined with other urine chemistry results received from an LIS. It produces quantitative or qualitative counts of all formed sediment elements present in urine, including cells, casts, crystals, and organisms. A competent human operator can set criteria for auto-reporting and flagging specimens for review. All instrument analyte image decisions may be reviewed and overridden by a trained technologist.

VI INDICATIONS FOR USE COMPARISON

The iQ200 System has the same indications for use as the previously cleared version, with the sole change being the discontinuation of the optional Lamina Cradle accessory (K093861). This modification does not constitute a new intended use, thereby maintaining the existing intended use and claims.

VI. TECHNOLOGICAL COMPARISON

The Lamina Cradle, an optional accessory introduced in K093861, has been discontinued. This discontinuation has no impact on the technological characteristics, such as design, material, chemical composition, principle of operation, and energy source, of the iQ200 Series when compared to predicate devices.

VII. NON-CLINICAL AND/OR CLINICAL TESTS SUMMARY

This section is not applicable since there were no changes to the existing performance section.

VIII. CONCLUSIONS

In summary, the iQ200 System, despite the discontinuation of the Lamina Cradle as described in this submission, is substantially equivalent in terms of safety and effectiveness to the predicate device.