



**510(k) SUBSTANTIAL EQUIVALENCE DETERMINATION
DECISION SUMMARY
INSTRUMENT ONLY**

I Background Information:

A 510(k) Number

K200811

B Applicant

Roche Diagnostics

C Proprietary and Established Names

Cobas u 701 Microscopy Analyzer

D Regulatory Information

Product Code(s)	Classification	Regulation Section	Panel
LKM	Class II	21 CFR 864.5200 - Automated Cell Counter	HE - Hematology

II Submission/Device Overview:

A Purpose for Submission:

Clearance of a new device

B Type of Test:

Microscopic analysis of formed elements in urine. The analyzer quantitates the following parameters: Red Blood Cells (RBC) and White Blood Cells (WBC), semi-quantitates determination of squamous epithelial cells, bacteria, and hyaline casts and qualitative determination of non-squamous epithelial cells, crystals, yeasts, pathological casts, mucus and sperm in urine.

III Intended Use/Indications for Use:

A Intended Use(s):

See Indications for Use below.

B Indication(s) for Use:

The cobas u 701 microscopy analyzer is a fully automated urine microscopy system intended for the in vitro quantitative determination of erythrocytes and leukocytes, the semi-quantitative determination of squamous epithelial cells, bacteria, and hyaline casts and the qualitative determination of non-squamous epithelial cells, crystals, yeasts, pathological casts, mucus and sperm in urine. These measurements are useful in the evaluation of renal, urinary and metabolic disorders.

This system is intended to be used by trained operators in clinical laboratories. All instrument analyte image decisions may be reviewed and reclassified by a trained operator.

C Special Conditions for Use Statement(s):

Rx - For Prescription Use Only

IV Device/System Characteristics:

A Device Description:

The cobas u 701 is a fully automated urine particle analyzer that is used in the clinical laboratory to analyze formed elements in urine samples quantitatively, semi-quantitatively and qualitatively for the presence of particles in the sample. The cobas u 701 microscopy analyzer is a stand-alone system and incorporates a robotic liquid handling system that pipettes an aliquot of the specimen into a disposable cuvette. The filled cuvette is forwarded to the built-in centrifuge for centrifugation of the non-soluble particles. After the centrifugation, all particles are brought to one monolayer to ensure they are all at the same focal plane. A built-in camera takes pictures through a built-in microscope at several positions of the sediment. All images are evaluated by an image processing software which is able to detect and further classify the following urine particles. Particle concentration is calculated using the average count from the assessed images. The cobas u 701 reports analysis results for two quantitative parameters in urine: RBC and WBC, three semi-quantitative parameters: SEC (Squamous epithelial cells), HYA (Hyaline casts) and BAC (Bacteria), and six qualitative parameters: NEC (Non-squamous epithelial cells), PAT (Pathological casts), CRY (Crystals), YEA (Yeast), SPRM (Sperm) and MUC (Mucus). The cobas u 701 microscopy analyzer performs a maximum theoretical throughput of up to 116 samples per hour.

The cobas u 701 consists of several major components:

- Rack transport system
- Liquid handling system
- Cuvette cassette compartment
- Centrifuge
- Built-in reverse microscope with movable objective lens for focusing procedure
- High resolution camera system
- Touch Screen
- Inbuilt Computer with the imaging and evaluation software for analyzing the sediment pictures

The cobas u cuvette is a cassette, containing cuvettes for the in vitro quantitative determination of erythrocytes and leukocytes, the semi-quantitative determination of squamous epithelial cells,

bacteria, and hyaline casts and the qualitative determination of non-squamous epithelial cells, crystals, yeasts, pathological casts, mucus, and sperm in urine with the cobas u 701 microscopy analyzer. The cobas u cuvette is for professional use only.

The cobas u cuvette is used by the cobas u 701 microscopy analyzer to transport, centrifuge and analyze patient and control samples. They are provided separately from the analyzer, in a box holding 400 disposable cuvettes.

Instrument Description Information:

1. Instrument Name:

cobas u 701 microscopy analyzer

2. Specimen Identification:

Human urine

3. Specimen Sampling and Handling:

The analyzer auto-identifies and processes barcoded tube specimens in 5-position racks by mixing, sampling, and analyzing automatically.

4. Calibration:

No calibration of the device is necessary for its intended use. However, there is a microscope check, which is not a calibration of the device. This microscope check ensures proper functioning of the focusing mechanism of the microscope utilizing a reference cuvette. The reference cuvette is a cuvette with the same dimensions as the sample cuvette, which contains a transparent material with a standardized number of erythrocyte like particles etched in it. For differentiation from the sample cuvettes, the reference cuvette is green and marked with the letter R on the top. This microscope check confirms that the instrument is able to focus accurately on the position of the particles and to count correctly the number of the cells. This microscope check needs to be performed every 4 weeks. A message from the instrument informs the operator when it is due.

5. Quality Control:

Recommendation of commercially available control solutions.

V Substantial Equivalence Information:

A Predicate Device Name(s):

Iq 200 System

B Predicate 510(k) Number(s):

K022774

C Comparison with Predicate(s):

Device & Predicate Device(s):	<u>K200811</u>	<u>K022774</u>
Device Trade Name	cobas u 701 microscopy analyzer	IRIS Iq 200
General Device Characteristic Similarities		
Intended Use/Indications for Use	The cobas u 701 microscopy analyzer is a fully automated urine microscopy system intended for the in vitro quantitative determination of erythrocytes and leukocytes, the semi-quantitative determination of squamous epithelial cells, bacteria, and hyaline casts and the qualitative determination of non-squamous epithelial cells, crystals, yeasts, pathological casts, mucus and sperm in urine. This system is intended to be used by trained operators in clinical laboratories. All instrument analyte image decisions may be reviewed and reclassified by a trained operator.	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.
Specimen Type	Random Urine Specimen	Same
Specimen Aspiration	Urine in barcode labeled tubes	Same
Change of machine assignment	An appropriately trained laboratory operator may manually re-classify or (sub-) sub-classify particles.	Same
Maintenance	Daily and periodic maintenance	Same
General Device Characteristic Differences		
Principle of Operation	The analyzer auto-identifies and	The iQ200 System auto-

	processes barcoded tube specimens in 5-position racks by mixing, sampling, and analyzing automatically. cobas u 701 microscopy analyzer incorporates a robotic liquid handling system that pipettes an aliquot of the specimen into a disposable cuvette. The filled cuvette is forwarded to the built-in centrifuge for centrifugation of the non-soluble particles. After the centrifugation, all particles are brought to one monolayer to ensure they are all at the same focal plane. A built-in camera takes pictures through a built-in microscope at several positions of the sediment. All images are evaluated by an image processing software which is able to detect and further classify the following urine particles •Red blood cells •White blood cells •Squamous epithelial cells •Bacteria •Hyaline casts •Non-squamous epithelial cells •Crystals •Yeast •Pathological casts •Mucus •Sperm An appropriately trained laboratory user may manually re-classify or sub-classify particles on the basis of the acquired pictures. Particle concentration is calculated using the average count from the assessed images.	identifies and processes barcoded tube specimens in 10-position racks by mixing, sampling, and analyzing automatically. The iQ200 system incorporates an iQ200 Automated Urine Microscopy Analyzer, in which a sample is presented as a lamina sandwiched between enveloping layers of suspending fluid to a microscope coupled to a CCD (charge coupling device) video camera. This lamination positions the specimen exactly within the depth of focus and field of view of the objective lens of the microscope. Lamination is the planar equivalent of axial hydrodynamic focusing, used to position cells in certain types of blood cell counters and flow cytometers. It has the added advantage of achieving orthoscopic particle orientation, thereby presenting asymmetric particles with their largest profile facing the direction of view. A CCD digital camera captures five hundred frames per sample, as each microscopic field of view is illuminated by the flash of a strobe lamp. The resulting pictures are digitized and delivered to the Analysis Processor computer. A previously stored image of a blank background is subtracted from the individual fields of view, enhancing the morphology of the captured particle. Individual particle images are isolated within each frame. The Auto-Particle Recognition
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		(APR™) software, a highly trained neural network, uses size, shape, contrast and texture features to classify each image into one of 12 categories: RBCs, WBCs, WBC Clumps, Hyaline Casts, Unclassified Casts, Squamous Epithelial Cells, Non-squamous Epithelial Cells, Bacteria, Yeast, Crystals, Mucus and Sperm. Particle concentration is calculated using the number of images and the volume scanned. User-defined release criteria are checked and results are sent to an operator review screen or directly uploaded to the LIS based on these criteria. Specimen results can be edited, archived, retrieved, imported, exported and formatted into custom reports
Detected and counted particles present in a specimen	•Red blood cells •White blood cells •Squamous epithelial cells •Bacteria •Hyaline casts •Non-squamous epithelial cells •Crystals •Yeast •Pathological casts •Mucus •Sperm It is possible to manually sub-classify particles (e.g. RBC morphologies, CRY) It is possible to manually identify further particles (e.g. trichomonas, red blood cell clumps, oval fat	•Red Blood Cells •White Blood Cells •White Blood Cell Clumps •Non-Squamous Epithelial Cells •Squamous Epithelial Cells •Hyaline Casts •Bacteria •Crystals •Yeast •Artifact •Unclassified Casts It is possible to manually sub-classify Unclassified Crystals, Unclassified Casts, Yeast and Non-Squamous Epithelial Cells. It is possible to manually identify the following particles •Sperm

	bodies, artifacts).	•Mucus •Trichomonas •Fat Red Blood Cell Clumps •Oval Fat Bodies
QC	Recommendation of commercially available control solutions	IQ Control material
Calibration	No calibration needed due to different particle detection technology	Monthly focus with iQ Focus and calibration with IQ Calibrator Material (suspension of fixed human red blood cells in a particulate-free solution)
Specimen Volume	Minimum volume 2 mL of un-spun urine. Aspiration volume < 0.8 mL	Minimum volume 3 mL of un-spun urine. Aspiration volume approx. 1.3 mL
Measurement Principle	Digital imaging after automated centrifugation	Flow digital imaging
Fluid Waste	Waste container capacity is 5L. This capacity is sufficient to run 400 tests. A direct waste discharge is possible (max. height = instrument level)	Waste is pumped from the instrument to a sink, floor drain or suitable container. Drain must be below or at same height as bench and should be less than 10 feet (3 meters) from the back of the instrument

VI Standards/Guidance Documents Referenced:

CLSI EP05-A3, Evaluation of Precision of Quantitative Measurement Procedures; Approved Guideline – Third Edition

CLSI EP06-A, Evaluation of the Linearity of Quantitative Measurement Procedures: A Statistical Approach; Approved Guideline – Third Edition

CLSI EP12-A2, User Protocol for Evaluation of Qualitative Test Performance; Approved Guideline – Second Edition

CLSI EP17-A2, Evaluation of Detection Capability for Clinical Laboratory Measurement Procedures; Approved Guideline – Second Edition

CLSI EP28-A3c, Defining, Establishing, and Verifying Reference Intervals in the Clinical Laboratory; Approved Guideline – Third Edition

VII Performance Characteristics (if/when applicable):

A Analytical Performance:

1. Precision/Reproducibility:

a. Repeatability Study

Repeatability (within-run precision) was evaluated using 3 control samples and 3 residual natural urine specimens without preservatives around the low and high end of the analytical measuring range. All used specimen (controls, human samples) were measured in 2 runs, 21 determinations each, producing n = 42 results per specimen. Testing was conducted across two sites using a single analyzer at each site and four different cuvette lots. All predefined acceptance criteria were met.

Repeatability for Quantitative Parameters Using Controls

						Run 1			Run 2		
Site	Parameter	Number of Runs	N Total	Control Level*	Target Range (p/μL)	Mean (p/μL)	SD (p/μL)	CV (%)	Mean (p/μL)	SD (p/μL)	CV (%)
Site 1	RBC	2	42	1	0-25	0.00	0.00	NA	0.00	0.00	NA
Site 1	RBC	2	42	2	425-1280	803	39.4	4.91	764	54.2	7.10
Site 1	RBC	2	42	3	50-120	70.6	9.19	13.0	53.8	7.94	14.8
Site 1	WBC	2	42	1	0-25	0.00	0.00	NA	0.00	0.00	NA
Site 1	WBC	2	42	2	75-240	138	15.0	10.9	133	11.6	8.71
Site 1	WBC	2	42	3	50-70	59.1	5.37	9.09	51.5	7.57	14.7
Site 2	RBC	2	42	1	0-25	0.04	0.19	458	0.08	0.26	316
Site 2	RBC	2	42	2	425-1280	641	31.9	4.97	890	48.3	5.42
Site 2	RBC	2	42	3	50-120	76.4	8.45	11.1	112	10.7	9.52
Site 2	WBC	2	42	1	0-25	0.00	0.00	NA	0.00	0.00	NA
Site 2	WBC	2	42	2	75-240	131	11.5	8.78	146	10.4	7.13
Site 2	WBC	2	42	3	50-70	62.7	6.74	10.8	67.4	7.34	10.9

*BioRad Liquichek control levels include: Level 1, Level 2, Level 3 (Low positive control prepared by diluting Bio-Rad Level 1 and Level 2; obtained values for low pos controls depend on dilution factor).

Repeatability for Quantitative Parameters Using Human Samples

					Run 1			Run 2		
Site	Parameter	No. of Runs	N Total	Concentration	Mean (p/μL)	SD (p/μL)	CV (%)	Mean (p/μL)	SD (p/μL)	CV (%)
Site 1	RBC	2	42	Neg	0.75	0.98	129	1.17	1.05	89.8
Site 1	RBC	2	42	Low pos	17.4	4.90	28.1	80.3	16.8	20.9
Site 1	RBC	2	42	Pos	1336	155	11.6	899	48.0	5.34
Site 1	WBC	2	42	Neg	2.26	1.26	55.8	2.58	2.38	92.3
Site 1	WBC	2	42	Low pos	14.1	4.06	28.8	63.9	8.86	13.9
Site 1	WBC	2	42	Pos	813	29.2	3.59	631	29.0	4.59
Site 2	RBC	2	42	Neg	0.92	1.02	111	0.59	1.12	192
Site 2	RBC	2	42	Low pos	125	11.3	9.03	13.0	4.48	34.4
Site 2	RBC	2	42	Pos	989	74.4	7.52	1175	50.8	4.33

Site 2	WBC	2	42	Neg	0.53	0.82	154	0.00	0.00	NA
Site 2	WBC	2	42	Low pos	22.8	5.28	23.2	56.4	7.18	12.7
Site 2	WBC	2	42	Pos	496	56.6	11.4	620	90.2	14.5

*BioRad Liquicheck control levels include: Level 1, Level 2, Level 3 (Low positive control prepared by diluting Bio-Rad Level 1 and Level 2; obtained values for low pos controls depend on dilution factor).

Repeatability for Semi-Quantitative and Qualitative Parameters

Site	Parameter	No. of Runs	N Total	Concentration	Run 1			Run 2		
					Mean (p/μL)	SD (p/μL)	CV (%)	Mean (p/μL)	SD (p/μL)	CV (%)
Site 1	BAC	2	42	Neg	79.6	12.7	15.9	32.7	5.88	18.0
Site 1	BAC	2	42	Low pos	107	8.83	8.23	176	10.1	5.73
Site 1	BAC	2	42	Pos	2380	169	7.10	1175	38.3	3.26
Site 1	CRY	2	42	Neg	0.21	0.58	279	0.61	0.87	144
Site 1	CRY	2	42	Pos	22.5	7.07	31.5	81.7	19.1	23.4
Site 1	HYA	2	42	Neg	0.08	0.18	211	0.10	0.24	226
Site 1	HYA	2	42	Low pos	4.00	1.16	29.1	6.81	2.09	30.6
Site 1	HYA	2	42	Pos	14.4	3.40	23.7	15.4	3.62	23.5
Site 1	MUC	2	42	Neg	26.5	8.63	32.5	4.44	2.55	57.5
Site 1	MUC	2	42	Pos	298	41.1	13.8	618	88.1	14.3
Site 1	NEC	2	42	Neg	0.21	0.30	143	0.00	0.00	NA
Site 1	NEC	2	42	Pos	27.7	3.89	14.1	7.08	2.23	31.5
Site 1	PAT	2	42	Neg	0.08	0.30	357	0.02	0.10	458
Site 1	PAT	2	42	Pos	2.10	0.90	43.0	3.25	1.05	32.5
Site 1	SEC	2	42	Neg	0.21	0.58	279	0.00	0.00	NA
Site 1	SEC	2	42	Low pos	14.4	2.49	17.4	15.9	4.25	26.7
Site 1	SEC	2	42	Pos	44.4	14.3	32.2	67.2	14.9	22.1
Site 1	SPRM	2	42	Neg	0.04	0.13	316	0.00	0.00	NA
Site 1	SPRM	2	42	Pos	17.7	5.87	33.1	36.7	5.98	16.3
Site 1	YEA	2	42	Neg	0.06	0.16	251	0.00	0.00	NA
Site 1	YEA	2	42	Pos	16.6	4.98	30.1	14.9	3.87	26.1
Site 2	BAC	2	42	Neg	26.9	4.22	15.7	21.4	2.04	9.55
Site 2	BAC	2	42	Low pos	117	8.11	6.95	151	8.32	5.51
Site 2	BAC	2	42	Pos (2+)	239	13.8	5.80	250	10.4	4.17
Site 2	BAC	2	42	Pos	1612	30.1	1.87	845	55.0	6.52
Site 2	CRY	2	42	Neg	0.59	0.49	83.3	0.82	0.73	88.9
Site 2	CRY	2	42	Pos	62.2	7.13	11.5	26.5	4.89	18.5
Site 2	HYA	2	42	Neg	0.00	0.00	NA	0.02	0.10	458
Site 2	HYA	2	42	Low pos	2.89	1.33	46.0	3.86	1.32	34.2
Site 2	HYA	2	42	Pos	20.9	3.51	16.8	17.0	4.10	24.1
Site 2	MUC	2	42	Neg	0.63	1.21	192	9.32	4.72	50.6
Site 2	MUC	2	42	Pos	491	34.8	7.08	426	52.9	12.4
Site 2	NEC	2	42	Neg	0.04	0.13	316	0.02	0.10	458
Site 2	NEC	2	42	Pos	7.50	1.97	26.2	8.21	1.96	23.9
Site 2	PAT	2	42	Neg	0.00	0.00	NA	0.02	0.10	458
Site 2	PAT	2	42	Pos	10.9	2.29	21.0	7.56	1.72	22.8
Site 2	SEC	2	42	Neg	0.00	0.00	NA	0.02	0.10	458
Site 2	SEC	2	42	Low pos	10.5	3.07	29.1	14.8	3.21	21.7
Site 2	SEC	2	42	Pos	53.9	9.09	16.9	63.8	6.40	10.0
Site 2	SPRM	2	42	Neg	0.00	0.00	NA	0.00	0.00	NA
Site 2	SPRM	2	42	Pos	16.7	3.08	18.4	8.65	2.00	23.1
Site 2	YEA	2	42	Neg	0.00	0.00	NA	0.00	0.00	NA
Site 2	YEA	2	42	Pos	268	19.6	7.31	236	33.0	14.0

Note: CV (%) cannot be calculated when mean = 0; these instances are marked as NA.

b. Intermediate Precision

Intermediate precision was performed according to CLSI EP5-A3 to assess long-term precision of the cobas u 701 microscopy analyzer. However, due to the instability of the human urine samples, only control samples were measured for this study. This assessment was limited to the parameters included in the control material (RBC, WBC). All predefined acceptance criteria were met.

Intermediate Precision for Controls at Site 1

Site 1						Repeatability		Between-Run		Between-Day		Intermediate (Within-site)	
Parameter	Number of runs	N Total	Control Level	Mean (p/μL)	Target Value (p/μL)	SD	% CV	SD	% CV	SD	% CV	SD	% CV
RBC	2	84	1	0.105	0 - 25	0.33	317	0.14	130	0.00	0.00	0.36	343
RBC	2	84	2	751	425 - 1280	47.1	6.26	18.5	2.46	33.6	4.47	60.7	8.08
RBC	2	84	3	54.3	50 - 70	6.64	12.2	4.37	8.03	6.14	11.3	10.0	18.5
WBC	2	84	1	0.00	0 - 25	0.00	NA	0.00	NA	0.00	NA	0.00	NA
WBC	2	84	2	139	75 - 240	14.2	10.2	5.06	3.65	8.23	5.93	17.1	12.3
WBC	2	84	3	58.5	50 - 70	8.43	14.4	0.00	0.00	6.93	11.8	10.9	18.7

Note: Bio-Rad Liquichek control levels include: Level 1, Level 2, Level 3 (Low positive control prepared by diluting Bio-Rad Level 1 and Level 2); For Liquichek control Level 1 and Level 2 samples, Target Values are from package insert; For prepared low positive control samples, Target Values will be affected by the variability of the control material.

Intermediate Precision for Controls at Site 2

Site 2						Repeatability		Between-Run		Between-Day		Intermediate (Within-site)	
Parameter	Number of runs	N Total	Control Level	Mean (p/μL)	Target Value (p/μL)	SD	% CV	SD	% CV	SD	% CV	SD	% CV
RBC	2	84	1	0.15	0 - 25	0.49	334	0.00	0.00	0.27	187	0.56	383
RBC	2	84	2	813	425 - 1280	42.8	5.26	20.3	2.50	30.0	3.69	56.1	6.90
RBC	2	84	3	69.5	50 - 70	8.32	12.0	0.41	0.59	3.35	4.82	8.98	12.9
WBC	2	84	1	0.00	0 - 25	0.00	NA	0.00	NA	0.00	NA	0.00	NA
WBC	2	84	2	140	75 - 240	9.36	6.69	2.31	1.65	8.17	5.84	12.6	9.03
WBC	2	84	3	62.8	50 - 70	8.09	12.9	2.17	3.46	2.47	3.93	8.74	13.9

Note: Bio-Rad Liquichek control levels include: Level 1, Level 2, Level 3 (Low positive control prepared by diluting Bio-Rad Level 1 and Level 2); For Liquichek control Level 1 and Level 2 samples, Target Values are from package insert; For prepared low positive control samples, Target Values will be affected by the variability of the control material.

Intermediate Precision for Controls at Site 4 (Internal Site)

Site 4						Repeatability (Within-Run)		Between-Run		Between-Day		Intermediate (Within-Site)	
Parameter	Number of Runs	N Total	Control Level	Mean (p/μL)	Target Value (p/μL)	SD (p/μL)	% CV	SD (p/μL)	% CV	SD (p/μL)	% CV	SD (p/μL)	% CV
RBC	2	84	1	0.23	0 - 25	0.65	283	0.00	0.00	0.00	0.00	0.65	283
RBC	2	84	2	375	160 - 495*	18.7	5.00	15.3	4.09	21.5	5.75	32.4	8.65

RBC	2	84	3	63.4	50 - 70	6.99	11.0	4.01	6.32	0.00	0.00	8.05	12.7
WBC	2	84	1	0.00	0 - 25	0.00	NA	0.00	NA	0.00	NA	0.00	NA
WBC	2	84	2	170	75 - 240	13.8	8.13	0.00	0.00	6.90	4.05	15.5	9.09
WBC	2	84	3	58.8	50 - 70	6.56	11.1	1.85	3.14	0.00	0.00	6.81	11.6

Note: CV (%) cannot be calculated when mean = 0; these instances are marked as NA; Bio-Rad Liquichek control levels include: Level 1, Level 2, Level 3 (Low positive control prepared by diluting Bio-Rad Level 1 and Level 2); For Liquichek control Level 1 and Level 2 samples, Target Values are from package insert; For prepared low positive control samples, Target Values will be affected by the variability of the control material.

**This lot had a lower claim for the RBC in Level 2 than the two external sites

c. Reproducibility Study

Reproducibility measurements for quantitative parameters WBC and RBC were performed based on the compiled intermediate precision datasets for the three study sites each using one cobas u 701 microscopy analyzer.

Reproducibility for Combined Data from Three Sites

					Repeatability (Within-Run)		Between-Run		Between-Day		Reproducibility (Within-Site)		Between-Site		Reproducibility (Within-System)	
Parameter	N Total	Concentration Level	Mean (p/μL)	Target Value p/μL	SD (p/μL)	% CV	SD (p/μL)	% CV	SD (p/μL)	% CV	SD (p/μL)	% CV	SD (p/μL)	% CV	SD (p/μL)	% CV
RBC	252	1	0.16	0 - 25	0.51	316	0.00	0.00	0.09	56.4	0.52	321	0.03	21.1	0.52	322
RBC	252	2	846	425 - 1280	46.2	5.46	27.9	3.30	41.5	4.90	68.1	8.05	113	13.4	132	15.6
RBC	252	3	62.4	50 - 70	7.35	11.8	3.43	5.50	4.03	6.45	9.06	14.5	7.50	12.0	11.8	18.8
WBC	252	1	0.00	0 - 25	0.00	NA	0.00	NA	0.00	NA	0.00	NA	0.00	NA	0.00	NA
WBC	252	2	150	75 - 240	12.6	8.45	0.00	0.00	7.79	5.21	14.9	9.92	17.6	11.8	23.0	15.4
WBC	252	3	60.0	50 - 70	7.74	12.9	0.00	0.00	4.20	6.99	8.80	14.7	2.09	3.48	9.05	15.1

Note: CV (%) cannot be calculated when mean = 0; these instances are marked as NA

d. Recovery

Recovery measurements for semi-quantitative parameters BAC, HYA, and SEC were performed in triplicate on the cobas u 701 microscopy analyzer at two sites, each using one cobas u 701 microscopy analyzer. Additionally, one measurement was performed using the manual KOVA counting method. All predefined acceptance criteria were met.

Reproducibility for Semi-quantitative Parameters at Site 1

Parameter	Target Value	N	cobas u 701						KOVA	Exact Agreement	2 of 3 results within the specified concentration block	Agreement within 2 adjacent concentration ranges
			Raw Count (bacteria or p/μL)			Result			Result			
			1st	2nd	3rd	1st	2nd	3rd				
BAC	Negative (NaCl)	3	0.44	11.9	5.72	neg	neg	neg	neg	100	Yes	100
	1+	3	134	123	130	1+	1+	1+	1+	100	Yes	100
	2+	3	407	413	394	2+	2+	2+	2+	100	Yes	100
	3+	3	896	888	891	3+	3+	3+	3+	100	Yes	100
HYA	Negative (Urine)	3	0.00	0.00	0.00	neg	neg	neg	0.00	100	Yes	100
	5 p/μL	3	3.96	3.52	8.36	5	5	15	2.75	66.7	Yes	100

Parameter	Target Value	N	cobas u 701						KOVA	Exact Agreement	2 of 3 results within the specified concentration block	Agreement within 2 adjacent concentration ranges
			Raw Count (bacteria or p/μL)			Result			Result	[%]	[Yes/No]	[%]
			1st	2nd	3rd	1st	2nd	3rd				
	15 p/μL	3	12.8	11.4	12.8	15	15	15	13.8	100	Yes	100
SEC	Negative (Urine)	3	0.00	0.00	0.00	neg	neg	neg	0.00	100	Yes	100
	15 p/μL	3	11.0	16.3	13.6	15	15	15	13.2	100	Yes	100
	40 p/μL	3	43.1	55.0	50.6	40	40	40	52.8	100	Yes	100

Reproducibility for Semi-quantitative Parameters at Site 2

Parameter	Target Value	N	cobas u 701						KOVA	Exact Agreement	2 of 3 results within the specified concentration block	Agreement within 2 adjacent concentration ranges
			Raw Count (bacteria or p/μL)			Result			Result	[%]	[Yes/No]	[%]
			1st	2nd	3rd	1st	2nd	3rd				
BAC	Negative (NaCl)	3	2.64	4.84	1.76	neg	neg	neg	neg	100	Yes	100
	1+	3	169	157	170	1+	1+	1+	1+	100	Yes	100
	2+	3	496	565	533	2+	2+	2+	2+	100	Yes	100
	3+	3	1066	1280	1253	3+	3+	3+	3+	100	Yes	100
HYA	Negative (Urine)	3	0.00	0.00	0.00	neg	neg	neg	0.00	100	Yes	100
	5 p/μL	3	6.16	4.40	8.80	5	5	15	5.50	66.7	Yes	100
	15 p/μL	3	15.4	8.80	15.4	15	15	15	18.7	100	Yes	100
SEC	Negative (Urine)	3	0.88	0.88	0.44	neg	neg	neg	1.10	100	Yes	100
	15 p/μL	3	20.7	11.4	13.6	15	15	15	17.6	100	Yes	100
	40 p/μL	3	49.3	36.5	47.1	40	40	40	56.1	100	Yes	100

2. Linearity:

Linearity of the cobas u 701 microscopy analyzer was determined for the two quantitative parameters RBC and WBC using one lot of cobas u cuvette and one cobas u 701 instrument. Linear regression was calculated according CLSI EP6-A.

Urine specimen pools were created by diluting and spiking natural urine samples with human RBC and WBC particles to cover the full measuring range for each quantitative parameter. One dilution series was prepared for each parameter (RBC & WBC). The RBC linearity set consisted of 25 serial dilutions. The WBC linearity set consisted of 23 serial dilutions. Each dilution concentration was measured in 4-fold determination in a randomized order. For evaluation, every single result was plotted against expected concentrations. Then linearity regression was calculated according CLSI EP6-A by a statistical software tool. The results obtained for RBC and WBC using the cobas u 701 microscopy analyzer met the defined acceptance criteria. Data analysis showed linearity for RBC and WBC was achieved through polynomial regression. The linearity was confirmed for a linearity range for RBC from 5–2160 p/μL and WBC from 5–1080 p/μL. The measuring ranges for RBC (5–1800 p/μL) and WBC (5–900 p/μL) were covered by the linearity experiment.

3. Analytical Specificity/Interference:

The interference study assessed the potential interferences that may occur on the cobas u 701 microscopy analyzer due to its measurement technology; clinical samples were assessed for the individual interferents. The study was determined by using four instruments and nine cuvette lots, on 670 native urine samples. Because of the imaging technology on the cobas u 701 microscopy analyzer, testing according EP07-A2 considered only visual/physical interferents; interference of drugs or endogenous substances is not applicable. Interference was confirmed, if the analyzer classification result was different than the visual classification result (KOVA manual counting). Native human urine samples containing the following interfering particles were measured on the cobas u 701 microscopy analyzers: high concentrations of mucus strands, artifacts, clumps, cell fragments, dysmorphic cells, shining particles, crowded samples, diluted samples, highly viscous samples, and high turbidity (Intralipid) samples. Furthermore, challenging native urine samples including amorphous crystals and trichomonas were evaluated. Based on the technological characteristics of the manual microscopy method, when measuring the following particles in the sample on the cobas u 701 microscopy analyzer, there is the potential that an incorrect result may be obtained.

Potential interfering particles and results

Particle / Sample	Result on cobas u 701 microscopy analyzer
Mucus and artefacts	Particles may be underrepresented in samples with high amounts of mucus. Artifacts like fibers, hairs or dust may interfere with the result. Therefore, clean sampling and storage is important. A wrong classification of these particles can lead to false positive results. Large artefacts may cause defocused particles, which will be misclassified or not detected.
Clumps, fragments, aggregations, and dysmorphic cells	Clumps of cells, clumps of cell fragments, cell fragments of particles and or aggregations of particles may lead to misclassification. Also, dysmorphic cells may lead to a misclassification. Therefore, the standard sample stability and sample storage conditions should be followed. The sample itself should be mixed gently before testing.
Amorphous urates	Granules of amorphous urates with tendency to aggregate as coarse irregular dark masses may be detected as Bacteria (BAC). This depends on the size of the urates. Urates are a subclass of crystals (CRY) and should be identified as CRY within the image. If the crystals are really small, they may be detected as BAC. BAC is not labeled in the images as the estimation for BAC is based on the ratio of occupied to non-occupied space.
Misclassification of Bacteria	Certain forms of Bacteria (BAC) with a tendency to arrange in groups may be detected as Crystal (CRY) or Sperm (SPRM).
Shining particles	Shining particles sometimes may lead to misclassification.
Crowded samples	In case of high positive samples like RBC, WBC, SEC, BAC and CRY, where the images are crowded, the particles with high concentration may obscure those of lower concentration. This is due to the fact that the particles are centrifuged to a single layer, the focal plane. Such samples are not evaluated by the algorithm, they are marked with an "Uc" and must be reviewed by the user. If the concentration of the quantitative parameters exceeds 1800 p/μL for RBC or 900 p/μL for WBC, the samples are marked with "O" (Parameter is out of range).

Diluted samples	Dilution of samples may cause cell lysis. The degree of cell lysis depends on the osmotic pressure of the diluted sample. Dilution may cause misclassification due to changes in cell size or shape or the decrease in number of the cells.
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4. Accuracy (Instrument):

To assess the accuracy of the cobas u 701 microscopy analyzer, a method comparison study was performed versus manual counting using KOVA chamber as the defined reference method was performed utilizing clinical samples. Six cobas u cuvette lots and one cobas u 701 instrument per site were used to perform the measurements. Measurements were performed at three sites, each using one cobas u 701 instrument per site and six cobas u cuvette lots. Statistical analysis was then performed comparing the cobas u 701 results and the KOVA chamber results.

Patient demographics included both males and females ranging in age from 1 month old to 98 years of age (355 females, 334 males and 91 pediatrics). A total of 168 subjects with known clinical conditions (kidney, infectious, and metabolic diseases) and 521 subjects with either healthy or unknown clinical condition urine samples were tested. For quantitative parameters, regression analysis (Passing-Bablok), including 95% confidence intervals (CI) and estimates of the bias/difference were calculated for each parameter. In addition, Bland-Altman plots were generated to show the differences between the two devices for all reportable parameters. For both semi-quantitative and qualitative parameters, the agreement rates, including positive percentage agreement (PPA), negative percentage agreement (NPA) and the lower end 95% confidence limits were calculated.

The results of the method comparison studies performed between cobas u 701 microscopy analyzer and visual counting using the KOVA chamber are shown below. All obtained statistical results from the single sites as well as for the compiled data sets were within the defined specifications and confirmed the substantial equivalence of the automated cobas u 701 microscopy analyzer with the manual KOVA counting method.

Method Comparison – Passing-Bablok Regression Analysis for Quantitative Parameters

Site	Parameter	N*	Range of values		Passing Bablok regression		Pearson's			Agreement rates (%)**	
			cobas u 701	KOVA	Slope (LCL, UCL)	Intercept (LCL, UCL)	r	R ²	p=value (r=0)	Neg	Pos
All sites	RBC	305	5–1746	5–1769	1.00 (0.99, 1.01)	-0.67 (-1.65, 0.16)	0.99	0.97	<0.001	99%	92%
	WBC	384	5–806	5–875	0.98 (0.97, 0.99)	-0.99 (-1.91, 0.04)	0.98	0.97	<0.001	98%	98%
Site 3	RBC	84	6 - 1639	5 - 1710	1.02 (1.01, 1.04)	2.60 (-0.09, 3.61)	0.99	0.98	<0.001	99%	100%
	WBC	111	5 - 804	5 - 806	1.01 (0.98, 1.03)	1.81 (-0.62, 2.42)	0.99	0.97	<0.001	98%	100%
Site 2	RBC	90	5 - 1585	5 - 1769	1.00 (0.99, 1.01)	0.84 (-0.75, 2.35)	0.99	0.98	<0.001	99%	96%
	WBC	140	5 - 781	5 - 801	0.97 (0.94, 0.99)	-0.06 (-1.63, 0.49)	0.99	0.97	<0.001	99%	97%
Site 1	RBC	131	5 - 1746	6 - 1753	0.93 (0.90, 0.96)	-1.26 (-3.19, -0.50)	0.98	0.96	<0.001	98%	83%
	WBC	133	5 - 806	6 - 875	0.94 (0.90, 0.97)	-1.77 (-3.13, -0.69)	0.98	0.97	<0.001	98%	98%

*includes all data within the defined measuring range on **cobas u 701**

**negative agreement calculation includes results below measuring range for RBC / WBC

Method Comparison – Agreement Rates for Semi-quantitative Parameters

Parameter	All sites			
	N	NPA (LCL)	PPA (LCL)	Cohen's Kappa
BAC	680	97% (95%)	95% (93%)	0.88
SEC	670	97% (95%)	99% (96%)	0.86
HYA	672	98% (97%)	94% (89%)	0.83

NPA = negative percentage agreement; PPA = positive percentage agreement; LCL = lower confidence limit

Method Comparison – Agreement Rates for Qualitative Parameters

Parameter	All sites			
	N	NPA (LCL)	PPA (LCL)	Cohen's Kappa
CRY	670	97% (95%)	98% (93%)	0.95
MUC	670	99% (98%)	94% (91%)	0.93
NEC	675	90% (88%)	94% (88%)	0.84
PAT	670	93% (91%)	89% (80%)	0.82
SPRM	670	95% (93%)	94% (85%)	0.89
YEA	670	97% (95%)	91% (82%)	0.88

NPA = negative percentage agreement; PPA = positive percentage agreement; LCL = lower confidence limit

Predicted bias at medical decision levels, low, middle, and high ends of measurement ranges for RBC and WBC are provided in tables below.

RBC Predicted Bias at Medical Decision Levels

Study Site:	Concentration [p/μL]	Bias	Bias (95% LCL)	Bias (95% UCL)
All sites	10	-0.63 p/μL	-1.44 p/μL	0.08 p/μL
	15	-0.61 p/μL	-1.45 p/μL	0.06 p/μL
	100	-0.30 %	-1.72 %	0.56%
	500	0.24 %	-1.13 %	1.23 %
	1000	0.30 %	-1.06 %	1.32 %
	1500	0.33 %	-1.04 %	1.36 %
Site 1	10	-1.99 p/μL	-3.81 p/μL	-1.48 p/μL
	15	-2.35 p/μL	-4.15 p/μL	-1.83 p/μL
	100	-8.56 %	-12.2 %	-4.31 %
	500	-7.55 %	-11.0%	-2.73 %
	1000	-7.43 %	-10.9 %	-2.53 %
	1500	-7.39 %	-10.9 %	-2.48 %
Site 3	10	2.83 p/μL	0.36 p/μL	4.50 p/μL
	15	2.94 p/μL	0.48 p/μL	4.60 p/μL
	100	4.86 %	1.53 %	6.86 %
	500	2.78 %	0.63 %	4.59 %
	1000	2.52 %	0.50 %	4.36 %
	1500	2.43 %	0.46 %	4.28 %
Site 2	10	0.86 p/μL	-0.59 p/μL	2.29 p/μL

	15	0.88 p/μL	-0.54 p/μL	2.23 p/μL
	100	1.07 %	-0.87 %	2.51 %
	500	0.40 %	-1.43 %	1.75 %
	1000	0.32 %	-1.54 %	1.69 %
	1500	0.30 %	-1.58 %	1.67 %

WBC Predicted Bias at Medical Decision Levels

Study Site:	Concentration [p/μL]	Bias	Bias (95% LCL)	Bias (95% UCL)
All sites	25	-1.47 p/μL	-2.32 p/μL	-0.57 p/μL
	100	-2.93 %	-4.37 %	-1.52 %
	200	-2.43 %	-3.78 %	-1.10 %
	400	-2.18 %	-3.62 %	-0.84%
	800	-2.06 %	-3.52 %	-0.68%
Site 1	25	-3.31 p/μL	-4.79 p/μL	-2.20 p/μL
	100	-7.91 %	-13.00%	-4.49 %
	200	-7.02 %	-12.2 %	-3.43 %
	400	-6.58 %	-11.9 %	-2.81 %
	800	-6.35 %	-11.7 %	-2.53 %
Site 3	25	2.01 p/μL	-0.94 p/μL	2.76 p/μL
	100	2.60%	-1.38 %	4.23 %
	200	1.70%	-1.33 %	3.55 %
	400	1.24 %	-1.47 %	3.40 %
	800	1.02 %	-1.57 %	3.39 %
Site 2	25	-0.84 p/μL	-2.55 p/μL	-0.20 p/μL
	100	-3.19 %	-6.35 %	-0.75 %
	200	-3.16 %	-6.39 %	-0.47 %
	400	-3.15 %	-6.49 %	-0.33 %
	800	-3.14 %	-6.54 %	-0.28 %

5. Carry-Over:

Carryover was evaluated by testing residual urine samples without preservatives with high RBC, WBC, BAC, SEC, HYA, YEA, SPRM, and CRY at two sites, using five cobas u cuvette lots and one cobas u 701 instrument per site. First, a negative sample was measured in 25 determinations (reference run). Afterwards, sample blocks with five samples each were measured in alternate measurement mode. Alternating measurements of samples with high and negative concentrations were performed, meaning a high concentration sample block (n=5) was measured, then a negative sample block (n=5) was measured, and then a high concentration sample block was measured (n=5), etc.

Each block was measured 5 times for a total of 25 results for the high sample and 25 results for the negative sample. Statistical calculations for the quantitative parameters comprised calculation of mean and standard deviation for the reference run. For the semi-quantitative

and qualitative parameters, the results of the negative samples after positive sample testing were assessed to confirm that they were still “negative”. The results of the Sample Carry-over assessment for the defined parameters performed on the cobas u 701 microscopy analyzer using the cobas u cuvette met the predefined acceptance criteria.

B Other Supportive Instrument Performance Characteristics Data:

1. Detection Limit:

Limit of Blank (LoB)

Limit of Blank (LoB) of the cobas u 701 microscopy analyzer was determined using one lot of cobas u cuvette and three cobas u 701 microscopy analyzers. The LoB is the highest observed measured value for samples free of analyte. The Limit of Blank was determined as the 95th percentile of the measurement of blank samples. Five samples per analyte were prepared fresh every day and tested on 3 days. Each day, two runs were performed with five samples measured in singlicate per run. Thirty results were collected for each parameter on each instrument for a total of 90 results per parameter. To determine the LoB, the 90 results for each parameter were sorted low to high. Using the nonparametric approach, determination of the 95th percentile was calculated from the mean of the 85th and 86th ranked results. All predefined acceptance criteria were met. The LoB was determined as follows:

Parameter	Units	LoB Result
RBC	RBC/ μ L	0.0
WBC	WBC/ μ L	0.0
SEC	SEC/ μ L	0.0
HYA	HYA/ μ L	0.0
BAC	BAC/ μ L	2

Limit of Detection (LoD)

Limit of Detection (LoD) of the cobas u 701 microscopy analyzer was determined using one lot of cobas u cuvette and three cobas u 701 microscopy analyzers. LoD determines the detection limit for samples with low analyte concentration. The LoD was determined as the lowest amount of analyte in a sample that can be detected with a 95% probability. Five samples per parameter were measured. Each sample was measured in a 10-fold determination on each of the three analyzers. Measurements were performed on minimum 3 days. In total, 150 results were collected for each parameter. All predefined acceptance criteria were met. The LoD was calculated as follows:

$$\text{LoD} = \text{LoB} + (1.648 \times \text{SD})$$

Parameter	Units	LoD Result
RBC	RBC/ μ L	4.0
WBC	WBC/ μ L	3.0
SEC	SEC/ μ L	4.0
HYA	HYA/ μ L	1.4
BAC	BAC/ μ L	1.9

Limit of Quantitation (LoQ)

Limit of Quantitation (LoQ) of the cobas u 701 microscopy analyzer was determined using one lot of cobas u cuvette and three cobas u 701 microscopy analyzers. LoQ is defined as the lowest analyte concentration in a sample that can be reproducibly measured. LoQ was determined for the quantitative parameters RBC and WBC with the same set of samples applied for the LoD determination. LoQ for RBC and WBC parameters met the predefined acceptance criteria.

Parameter	LoQ Result	Measuring Range Claim
RBC	4.0 p/μL	5 – 1800 p/μL
WBC	3.1 p/μL	5 – 900 p/μL
SEC	6.9 p/μL	neg 1+ 2+ neg 15 40 p/μL
HYA	1.4 p /μL	neg 1+ 2+ neg 5 15 p/μL
BAC	99.6 p/μL	neg 1+ 2+ 3+

2. Traceability, Stability, Expected Values (Controls, Calibrators, or Methods):

Calibration:

No calibration of the device is necessary due to different particle detection technology. However, there is a microscope check, which is not a calibration of the device. This microscope check ensures proper functioning of the focusing mechanism of the microscope utilizing a reference cuvette. This microscope check needs to be performed every 4 weeks. A message from the instrument informs the operator when it is due.

Quality control:

Recommendation of commercially available control solutions.

3. Sample Stability:

Sample stability testing was performed using anonymized fresh human urine samples and measuring these samples at three different time points: 1) T0 - 0 h sample lifetime; 2) T1 - 2 h sample lifetime, and; 3) T2 - 3 h sample lifetime.

The urine samples were divided into four aliquots, thereof one for each time point and one for visual determination of the parameters SG (specific gravity) and pH with Chemstrip 10 UA test strips. Prior to and between the measurements of the different time points, the samples were stored at room temperature. For each testing point, a 4-fold determination was performed of urine samples on the cobas u 701 microscopy analyzer to rule out imprecision effects, unrelated to the analyte stability. In parallel to the instrument reading, a single determination with Chemstrip 10 UA was done at each time point of the same sample to determine the SG and pH values. The results obtained for sample stability using the cobas u 701 microscopy analyzer met the defined acceptance criteria. The pH and SG measured values remain unchanged over the entire measuring time. Data analysis showed sample stability for negative and positive flagged samples passed at time T2 (3 h) when stored at room temperature, one time-point below the sample stability claim of 2 hours.

4. Assay Cut-Off:

For semi-quantitative and qualitative assay cut-off determination, range limits were set using empirical and theoretical information from literature, knowledge from clinical practice and the available data from external performed studies.

Definition of comparison of cobas u 701 and KOVA ratings

Parameter	Reported unit		cobas u 701 Range Limit [p/μl]	Kova Range Limit [p/μl]
	Arbitrary	Conventional		
BAC				
1	neg	N/A	≤ 100.0	≤ 0.5*
2	1+	N/A	> 100.0 ≤ 220.0	> 0.5 ≤ 1.5*
3	2+	N/A	> 220.0 ≤ 750.0	> 1.5 ≤ 2.5*
4	3+	N/A	> 750.0	> 2.5*
NEC				
1	neg	N/A	≤ 1.4	≤ 3.0
2	pos	N/A	> 1.4	> 3.0
SEC				
1	N/A	neg	≤ 5.0	≤ 9.0
2	N/A	15	> 5.0 ≤ 25.0	> 9.0 ≤ 38.0
3	N/A	40	> 25.0	> 38.0
HYA				
1	N/A	neg	≤ 2.0	≤ 3.0
2	N/A	5	> 2.0 ≤ 8.0	> 3.0 ≤ 9.0
3	N/A	15	> 8.0	> 9.0
PAT				
1	neg	N/A	≤ 1.2	≤ 1.2
2	pos	N/A	> 1.2	> 1.2
CRY				
1	neg	N/A	≤ 5.0	≤ 5.0
2	pos	N/A	> 5.0	> 5.0
YEA				
1	neg	N/A	≤ 1.0	≤ 5.0**
2	pos	N/A	> 1.0	> 5.0**
MUC				
1	neg	N/A	≤ 100.0	≤ 5.0**
2	pos	N/A	> 100.0	> 5.0**
SPRM				
1	neg	N/A	≤ 0.80	≤ 5.0**
2	pos	N/A	> 0.80	> 5.0**

* arbitrary rating

** no real count result, only operator's rating of neg and pos: "0" indicates a negative, "10" a positive result (see table below)

N/A = parameter is not reported in those units

Example table of how a final result is calculated using only operator's ratings of "0" and "10"

Slide 1 / Operator 1	Slide 1 / Operator 2	Slide 2 / Operator 1	Slide 2 / Operator 2	Average	Result
0	0	0	0	0	Neg
0	0	0	10	2.5	Neg
0	0	10	10	5	Neg
0	10	10	10	7.5	Pos
10	10	10	10	10	Pos

5. Expected Values/Reference Range:

To establish reference values for RBC and WBC on the cobas u 701 microscopy analyzer, "urine healthy" residual samples were measured. Measurements were performed at three sites, each using one cobas u 701 microscopy analyzer and a total of four cobas u cuvette lots.

Reference Range Study Results for RBC

Site	Gender	N	Min	Max	Mean	Median	97.5 th percentile (90% CI)	99 th percentile (90% CI)
All sites combined	Female	310	0.00	7.92	1.20	0.88	6.16 (5.28, 7.92)	7.92 (6.16, 7.92)
	Male	311	0.00	9.68	1.13	0.00	6.16 (5.28, 7.92)	7.92 (6.16, 9.68)
	Total	621	0.00	9.68	1.16	0.00	6.16 (5.28, 7.92)	7.92 (7.04, 7.92)

Reference Range Study Results for WBC

Site	Gender	N	Min	Max	Mean	Median	97.5 th percentile (90% CI)	99 th percentile (90% CI)
All sites combined	Female	310	0.00	17.8	1.72	0.66	10.6 (7.26, 13.9)	13.2 (11.9, 17.8)
	Male	311	0.00	15.8	1.02	0.00	5.94 (5.28, 12.5)	9.90 (5.94, 15.8)
	Total	621	0.00	17.8	1.37	0.66	7.92 (5.94, 11.9)	12.5 (9.90, 16.5)

VIII Proposed Labeling:

The labeling supports the finding of substantial equivalence for this device.

IX Conclusion:

The submitted information in this premarket notification is complete and supports a substantial equivalence decision.