



U.S. Food and Drug Administration
Center for Devices and Radiological Health
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Tokyo Boeki Medical System Ltd.
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Re: k040958
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Categorization Notification

Regulations codified at 42 CFR 493.17 et. seq., implementing the Clinical Laboratory Improvement Amendments of 1988, require the Secretary to provide for the categorization of specific clinical laboratory test systems by the level of complexity. Based upon these regulations, the following commercially marketed test system or assay for the analyte is categorized below:

Test System/Analyte (s) : (SEE ATTACHMENT)

This complexity categorization is effective as of the date of this notification and will be reported on FDA's home page <http://www.fda.gov/cdrh/clia>. This categorization information may be provided to the user of the commercially marketed test system or assay as specified for the analyte indicated. It will also be announced in a Federal Register Notice, which will provide opportunity for comment on the decision. FDA reserves the right to reevaluate and recategorize this test based upon the comments received in response to the Federal Register Notice.

If you change the test system name or your company's name or if a distributor's name replaces your name, you must request another categorization by sending in the revised labeling along with a letter to FDA referencing the document number above.

If you have any questions regarding this complexity categorization, please contact Ruth Chesler at 301-796-6140.

Sincerely yours,

Alberto Gutierrez, Ph.D.
Director
Office of *In Vitro* Diagnostic Device
Evaluation and Safety
Center for Devices and Radiological Health

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Test System: Carolina Liquid Chemistries Corp., Biolis 50i Superior clinical chemistry analyser
Analyte : Chloride
Complexity : MODERATE

Test System: AlfaMed, CARDiOLiS 50i clinical chemistry analyzer
Analyte : Chloride
Complexity : MODERATE

Test System: ThermoFisher Scientific CCD, MGC 500i clinical chemistry analyzer
Analyte : Chloride
Complexity : MODERATE

Test System: Carolina Liquid Chemistries Corp., Biolis 50i Superior clinical chemistry analyzer
Analyte : Potassium
Complexity : MODERATE

Test System: AlfaMed, CARDiOLiS 50i clinical chemistry analyzer
Analyte : Potassium
Complexity : MODERATE

Test System: Thermo Fisher Scientific CCD, MGC 500i clinical chemistry analyzer
Analyte : Potassium
Complexity : MODERATE

Test System: Carolina Liquid Chemistries Corp., Biolis 50i Superior clinical chemistry analyzer
Analyte : Sodium
Complexity : MODERATE

Test System: AlfaMed, CARDiOLiS 50i clinical chemistry analyzer
Analyte : Sodium
Complexity : MODERATE

Test System: Thermo Fisher Scientific CCD, MGC 500i clinical chemistry analyzer
Analyte : Sodium
Complexity : MODERATE

Test System: Carolina Liquid Chemistries Corp., Biolis 50i clinical chemistry analyzer
Analyte : Glucose
Complexity : MODERATE

Test System: AlfaMed, CARDiOLiS 50i clinical chemistry analyzer
Analyte : Glucose
Complexity : MODERATE

Test System: Thermo Fisher Scientific CCD, MGC 500i clinical chemistry analyzer
Analyte : Glucose
Complexity : MODERATE

Test System: Sekisui Diagnostic LLC., Biolis 50i Superior clinical chemistry analyser
Analyte : Chloride
Complexity : MODERATE

Test System: Alere San Diego Inc., Biolis 50i Superior clinical chemistry analyser
Analyte : Chloride
Complexity : MODERATE

Test System: Sekisui Diagnostics LLC., Biolis 50i Superior clinical chemistry analyzer
Analyte : Potassium
Complexity : MODERATE

Test System: Alere San Diego Inc., Biolis 50i Superior clinical chemistry analyzer
Analyte : Potassium
Complexity : MODERATE

Test System: Sekisui Diagnostics LLC., Biolis 50i Superior clinical chemistry analyzer
Analyte : Sodium
Complexity : MODERATE

Test System: Alere San Diego Inc., Biolis 50i Superior clinical chemistry analyzer
Analyte : Sodium
Complexity : MODERATE

Test System: Sekisui Diagnostics LLC., Biolis 50i clinical chemistry analyzer
Analyte : Glucose
Complexity : MODERATE

Test System: Alere San Diego Inc., Biolis 50i clinical chemistry analyzer
Analyte : Glucose
Complexity : MODERATE
