

CAROLINA LIQUID CHEMISTRIES
TECHNICAL BULLETIN
FEBRUARY 2010

This bulletin is meant to provide you with documentation to confirm the 510 clearance of the Tokyo Boeki Medical System, LTD. In Akiruno, Japan, BioLis 24i.

Carolina Liquid Chemistries, the exclusive, U.S. supplier of Tokyo Boeki Medical System benchtop chemistry, has been informed that the BioLis 24i has been cleared for marketing via US FDA 510k number K040958 on February 15, 2005 under the names of Prestige 24i, Prestige 400, and MGC 240. Tokyo Boeki's 510k submission annotates these as the Proprietary and Established names of the analyzer. Further annotation states that "*These are the same models except the names.*"

The US FDA Web site link to verify this information is:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfpmn/pmn.cfm?ID=14915>

To answer the questions "*Why isn't the Biolis 24i recorded in the US FDA 510k clearances?*" please refer to the US FDA Establishment Registration Device Listing database for Tokyo Boeki.

Tokyo Boeki lists the following Clinical Chemistry Analyzers on the US FDA Establishment Registration Device Listing Web page. Please note that these are the same analyzers under different names as cleared under the 510k number K040958. In summary, the BioLis 24i is the same instrument as all others listed below, simply another name.

BIOLIS 24I	MGC 240	SIRRUS	Biolis 24i Premium	Biolis 24iPremium Series
Diag Premium	LABMAX 240 Premium	MGC 240 Premium	Prestige 24I	Prestige 24i Premium
SAPPHIRE 400 Premium	SIRRUS Premium	SPA Premium	TMS-1024i Premium	TRX-7010

The US FDA Web site link to verify this information is:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfRL/rl.cfm>

You will have to type in ***Tokyo Boeki*** in the Establishment Name box. Please note that to have a device listing on the US FDA Establishment Registration Device Listing database the firm must have a cleared 510k number; in this case 510k number K040958.

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The Biolis (Prestige 24i) 510k clearance was for Ion Specific Electrolytes (ISE) Potassium, Chloride, and Sodium. Additional chemistries were submitted to the US FDA 510k Premarket Approval Process by Stanbio Laboratory of Boerne, Texas, US FDA Registration number 1616487. Stanbio submitted these additional chemistries under the requirements of Clinical Laboratory Improvement Amendments (CLIA) with Analyte Specialty and Complexity identifiers as **General Chemistry** and **Moderate** respectively.

The US FDA Web site link to verify this information is:

<http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfClia/Search.cfm>

You will have to type in **Stanbio** in the Test System/Manufacture box.

To summarize this information, the conclusion is that the Carolina Liquid Chemistries Biolis 24i, along with the ISE's and chemistry reagents are cleared by the FDA.

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