



U.S. Food and Drug Administration



CENTER FOR DEVICES AND RADIOLOGICAL HEALTH

[FDA Home Page](#) | [CDRH Home Page](#) | [Search](#) | [A-Z Index](#)[Questions?](#)

[510\(k\)](#) | [Registration & Listing](#) | [Adverse Events](#) | [PMA](#) | [Classification](#) | [CLIA](#)
[CFR Title 21](#) | [Advisory Committees](#) | [Assembler](#) | [Recalls](#) | [Guidance](#) | [Standards](#)

[New Search](#)[Back To Search Results](#)

Product Classification Database

Device	Azo-Dyes, Colorimetric, Bilirubin & Its Conjugates (Urinary, Non-Quant.)
Regulation Description	Urinary bilirubin and its conjugates (nonquantitative) test system.
Regulation Medical Specialty	Clinical Chemistry
Review Panel	Clinical Chemistry
Product Code	JJB
Submission Type	510(k) Exempt
Regulation Number	862.1115
Device Class	1
GMP Exempt?	No

Note: FDA has exempted almost all class I devices (with the exception of [Reserved Devices](#)) from the premarket notification requirement, including those devices that were exempted by final regulation published in the *Federal Registers* of December 7, 1994, and January 16, 1996. It is important to confirm the exempt status and any limitations that apply with [21 CFR Parts 862-892](#). Limitations of device exemptions are covered under 21 CFR xxx.9, where xxx refers to Parts 862-892.

If a manufacturer's device falls into a generic category of exempted class I devices as defined in [21 CFR Parts 862-892](#), a premarket notification application and FDA clearance is not required before marketing the device in the U.S. However, these manufacturers are required to register their establishment. Please see the [Registration and Listing website](#) for additional information.

Recognized Consensus Standard

- CLSI/ NCCLS GP14-A 1996 [Labeling of Home-Use In Vitro Testing Products; Approved Guideline](#)

Third Party Review

Not Third Party Eligible

Database Updated 02/06/2009

[CDRH Home Page](#) | [CDRH A-Z Index](#) | [Contact CDRH](#) | [Accessibility](#) | [Disclaimer](#)
[FDA Home Page](#) | [Search FDA Site](#) | [FDA A-Z Index](#) | [Contact FDA](#) | [HHS Home Page](#)

Center for Devices and Radiological Health / CDRH