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Product Classification Database

Device	Lipase-Esterase, Enzymatic, Photometric, Lipase
Regulation Description	Lipase test system.
Regulation Medical Specialty	Clinical Chemistry
Review Panel	Clinical Chemistry
Product Code	CHI
Submission Type	510(k) Exempt
Regulation Number	862.1465
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.

Third Party Review Not Third Party Eligible

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