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[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	Enzymatic Esterase--Oxidase, Cholesterol
Regulation Description	Cholesterol (total) test system.
Regulation Medical Specialty	Clinical Chemistry
Review Panel	Clinical Chemistry
Product Code	CHH
Submission Type	510(k) Exempt
Regulation Number	862.1175
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 Standards

- NCCLS C37-A [Preparation and Validation of Commutable Frozen Human Serum Pools as Secondary Reference Materials for Cholesterol Measurement Procedures; Approved Guideline](#)

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

Guidance Document

- Guidance for 510(k)s on Cholesterol Tests for Clinical Laboratory, Physicians' Office Laboratory, and Home Use

[Text](#) [PDF](#) 

Third Party Review

Not Third Party Eligible

Database Updated 02/06/2009

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