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### Product Classification Database

<b>Device</b>	Lipase Hydrolysis/Glycerol Kinase Enzyme, Triglycerides
<b>Regulation Description</b>	Triglyceride test system.
<b>Regulation Medical Specialty</b>	Clinical Chemistry
<b>Review Panel</b>	Clinical Chemistry
<b>Product Code</b>	CDT
<b>Submission Type</b>	510(k) Exempt
<b>Regulation Number</b>	<a href="#">862.1705</a>
<b>Device Class</b>	1
<b>GMP Exempt?</b>	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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