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ALCAT TEST KIT APROBADO POR LA FDA

ALCAT TEST®
E LA INTOLERANCIA ALIMENTARIA

1906 - 2006 FDA Centennial

U.S. Food and Drug Administration

Health & Human Services

Proprietary Device Name:	ALCAT TEST KIT
Common/Generic Device Name:	WHITE BLOOD CELL SIZE AND NUMBER TEST KIT
Classification Name:	WHOLE BLOOD PLASMA, ANTIGEN, ANTISERUM, CONTROL
Device Class:	1
Product Code:	DGQ
Regulation Number:	866.5700
Medical Specialty:	Immunology
Owner/Operator:	CELL SCIENCE SYSTEMS, LTD. CORP.
Owner/Operator Number:	9070941
Registered Establishment Name:	CELL SCIENCE SYSTEMS, LTD. CORP.
Establishment Registration Number:	1051901
Date of Listing:	02/23/05
Listing Status:	Active
Establishment Operations:	Manufacturer

http://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm?ID=2680

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Device	Whole Blood Plasma, Antigen, Antiserum, Control
Regulation Description	Whole human plasma or serum immunological test system.
Regulation Medical Specialty	Immunology
Review Panel	Immunology
Product Code	DGQ
Submission Type	510(K) Exempt
Regulation Number	866.5700
Device Class	1
Total Product Life Cycle (TPLC)	TPLC Product Code Report
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 Device Registration and Listing website for additional information.

Third Party Review	Not Third Party Eligible

Page Last Updated: 05/03/2013
Note: If you need help accessing information in different file formats, see Instructions for Downloading Viewers and Players.

[Code of Federal Regulations]
[Title 21, Volume 8]
[Revised as of April 1, 2012]
[CITE: 21CFR866.5700]

TITLE 21--FOOD AND DRUGS
CHAPTER I--FOOD AND DRUG ADMINISTRATION
DEPARTMENT OF HEALTH AND HUMAN SERVICES
SUBCHAPTER H--MEDICAL DEVICES

PART 866 -- IMMUNOLOGY AND MICROBIOLOGY DEVICES

Subpart F--Immunological Test Systems

Sec. 866.5700 Whole human plasma or serum immunological test system.

(a) *Identification.* A whole human plasma or serum immunological test system is a device that consists of reagents used to measure by immunochemical techniques the proteins in plasma or serum. Measurements of proteins in plasma or serum aid in the diagnosis of any disease concerned with abnormal levels of plasma or serum proteins, e.g., agammaglobulinemia, allergies, multiple myeloma, rheumatoid vasculitis, or hereditary angioneurotic edema.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in 866.9.

[47 FR 50823, Nov. 9, 1982, as amended at 59 FR 63007, Dec. 7, 1994; 66 FR 38793, July 25, 2001]