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CLIA record *K980908* and corresponding 510(K) Premarket Notification information

Test System Name	KDK CORPORATION LACTATE PRO SYSTEM (For OTC use)
Document Number	K980908
Analyte Name	Lactic Acid (Lactate)
Analyte Specialty	General Chemistry
Complexity	WAIVED
Effective Date	07/27/2001

510(k) Premarket Notification Database

Device Classification Name	Acid, Lactic, Enzymatic Method
510(K) Number	K980908
Regulation Number	862.1450
Device Name	LACTATE PRO SYSTEM
Applicant	KDK CORP. 57 Nishiaketa-Cho, Higashi-Kujo, Minami-Ku Kyoto, JA 601
Contact	Kazuo Iketaki
Classification Product Code	KHP
Date Received	03/10/1998
Decision Date	09/11/1998
Decision	Substantially Equivalent (SE)
Classification Advisory Committee	Clinical Chemistry
Review Advisory Committee	Clinical Chemistry