

**Fast**  
**Easy** **CardioChek ST & CardioChek PA**  
**Accurate** Home Cholesterol Testing Monitor Kits

**Regulatory Status Report: Updated 11/15/02**  
**510(k) Clearances and CLIA Waivers**

ITEM	Description	K Number	Status	Date First CLIA Waived
BioScanner 2000 Instrument	Instrument for all tests	K972669	Cleared Jan.22, 1998	Jul.17,1998
PTS PANELS Glucose Test Strips (Professional)	Glucose test	K972669	Cleared Jan.22, 1998	Jul.17, 1998
PTS PANELS Glucose Test Strips (OTC)	Glucose test	K972669	Cleared Jan.22, 1998	Jul.17, 1998
PTS PANELS Glucose Control	Glucose control	K972669	Cleared Jan.22, 1998	Does not apply
PTS PANELS Cholesterol (Professional)	Cholesterol test	K981493	Cleared July 22, 1998	
PTS PANELS Cholesterol (OTC)	Cholesterol test	K990688	Cleared June 24, 1999	Aug. 19, 1999
PTS PANELS Ketone (Professional)	Ketone test	K981865	Cleared Feb.26, 1999	Mar. 1, 2000
PTS PANELS Ketone (OTC)	Ketone test	K983860	Cleared Dec.27,1999	
PTS PANELS HDL (Professional)	HDL test	K990247	Cleared May 28, 1999	
PTS PANELS HDL (OTC)	HDL test	K993377	Cleared Jan.13, 2000	Feb.28,2000
PTS PANELS Triglycerides (Professional)	Triglyceride test	K991894	Cleared May 24, 2000	
PTS PANELS Triglycerides (OTC)	Triglyceride test	K000586	Cleared July 3, 2000	Jul. 3, 2000
PTS PANELS Creatinine Test Strips (Professional)	Creatinine test	K010456	Cleared June 20, 2001	
CardioChek (Professional)	Instrument for all tests	K013173	Cleared Oct. 22, 2001	

Lipid Panel Test Strips (Professional)	Multi-test strip for cholesterol, HDL, and triglycerides	K013173	Cleared Oct. 22, 2001	
Q3 Glucose Analyzer (Professional and OTC)	Hand-held amperometric glucose analyzer	K013203	Cleared Nov. 16, 2001	Nov. 16, 2001
BioScanner 2000 and PTS PANELS Test Strips	Glucose test	K013068	Cleared Nov. 20, 2001	Nov. 20, 2001
CardioChek Professional and OTC Glucoses	CardioChek with PTS PANELS Test Strips (colorimetric) and PTS PANELS Advanced Glucose Test Strips (amperometric)	K014099	Cleared Dec. 21, 2001	Dec. 21, 2001
PTS PANELS Multi-Chemistry Controls	Multi-constituent controls for use with PTS PANELS Test Strips	K022401	Cleared Aug. 21, 2002	Does not apply
PTS PANELS Lipid Panel Test Strips (Professional)	Multi-test strip for cholesterol, HDL, and triglycerides. Special 510 (k) with revised claims	K022898	Cleared Sept. 24, 2002	Oct. 18, 2002
PTS PANELS Lipid Panel Test Strips (OTC)	Multi-test strip for cholesterol, HDL, and triglycerides.	K023558	Cleared Nov. 15, 2002	Nov. 15, 2002

**Fast**  
**Easy** CardioChek ST & CardioChek PA  
**Accurate** Home Cholesterol Testing Monitor Kits