

510(k) CLEARANCES

Company	Date	510(k) Number	Tissue, Stain	Reagent	Application	CPT code
Aperio	8/2009	K080564	Breast-HER2, neu	Dako	Tunable Image Analysis	88361
Aperio	10/2008	K080254	Breast, PR	Dako	Manual read on a monitor	88360
Aperio	08/2008	K073667	Breast- ER/PR	Dako	Image Analysis	88361
Aperio	12/2007	K071671	Breast, HER2/neu	Dako	Manual read on a monitor	88360
Aperio	10/2007	K071128	Breast-HER2/ neu	Dako	Image Analysis	88361
Applied Imaging(owned by Danaher/Leica)	03/2004	K012138	Breast- ER/PR	Dako	Image Analysis	88361
Applied Imaging(owned by Danaher/Leica)	01/2004	K031715	Breast-HER2/ neu	Dako	Image Analysis	88361
Bioimagene (owned by Roche/Ventana)	10/2010	K092333	Breast- P53/Ki-67	Dako	Image Analysis	88361
Bioimagene (owned by Roche/Ventana)	02/2009	K080910	Breast-HER2/ neu	Dako	Image Analysis	88361
Bioimagene (owned by Roche/Ventana)	02/2007	K062756	Breast-HER2/ neu	Dako	Image Analysis, software only	88361
Cell Analysis	12/2003	K031363	Breast-ER	Dako	Image Analysis (software only)	88361
Clariant/Chromavision (owned by ZEISS)	02/2004	K012138	Breast- ER/PR	Dako	Image Analysis	88361
Clariant/Chromavision (owned by ZEISS)	12/2003	K032113	Breast-HER2/ neu	Dako	Image Analysis, System	88361

Company	Date	510(k) Number	Tissue, Stain	Reagent	Application	CPT code
Tripath (owned by Roche/Ventana)	09/2006	K062428	Breast- p53	Ventana	Image Analysis	88361
Tripath (owned by Roche/Ventana)	04/2006	K053520	Breast- Ki-67	Ventana	Image Analysis	88361
Tripath (owned by Roche/Ventana)	08/2005	K051282	Breast, HER2/neu	Ventana	Image Analysis	88361
Tripath (owned by Roche/Ventana)	05/2005	K050012	Breast- ER/PR	Ventana	Image Analysis	88361
Ventana Medical Systems	10/2011	K111543	Breast, HER2 (4B5)	Ventana	Image Analysis, & manual read	88360, 88361
Ventana Medical Systems	03/2012	K111869	Breast, PR (1E2)	Ventana	Image Analysis, & manual read	88360, 88361
Ventana Medical Systems	02/2012	K111755	Breast, Ki-67 (30-9)	Ventana	Image Analysis, & manual read	88360, 88361
Ventana Medical Systems	04/2012	K111872	Breast, p53 (DO-7)	Ventana	Image Analysis, & manual read	88360, 88361