Medical Device Security

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General System Counts

Systems with AV......6398
Printers................2074
Medical equipment...905
Misc....................2460

Total Devices:........11837

OS Makeup – Medical

Windows 95............1
Windows 98 ...........15
Windows 2000 .......23
Windows CE..........9
Windows Vista.......0
Windows XP..........600
Windows XP SP1.....0
Windows XP SP2.....15
Windows XP SP3.....1

Total....................664

Average Time to Infection

Clinical Systems , 510K, no AV...: 12 days
Systems running AV/Patches.....: 300+ days

Ideally:  FDA 510K is updated to include a requirement for the provision of industry accepted security controls for devices utilizing embedded operating systems or other controllers associated with a medical device

Alternatively: The FDA issues a clear statement to the community that FDA 510K is not jeopardized by permitting Anti-Virus or Operating System patching to the supporting systems associated with a certified medical device