510(k) Summary
for GORCA Medical Technologies StatNet
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Device Trade Name: **StatNet.**

Common name: Picture Archiving and Communication System (PACS)
              for cardiology departments.

Classification: Accessory to angiographic X-ray system (892.1600) or PACS, product code LLZ, consisting of a combination of medical image storage devices, product code LMB, and medical image communication devices, product code LMD, to which image processing and display functions have been added.

Predicate Device: Camtronics Archium manufactured by Camtronics Ltd., 900 Walnut Ridge Drive, Hartland, WI (K934496).

Description of Device:

StatNet is a network of image display, processing, and archiving modules composed of general purpose, personal computer level, digital hardware; commercial, general purpose digital communication hardware; general purpose operating systems and communications software; medical image analysis and processing software developed by others; and proprietary software modules developed by GORCA that integrate the preceding components into a complete system. Images enter the network on DICOM-3 CD-ROM media.

Intended Use of Device:

StatNet is intended for the storage, distribution to any of several work stations, viewing, interpretation and annotation of X-ray of coronary anatomy that have been obtained in coronary catheterization laboratories and written on DICOM-3 CD-ROM media.

Statement of Substantial Equivalence

	Function or Variable	STATnet	Predicate		
			IMACS	EIGEN	Camtronics
1	Electronic Equivalent of Cine Review	Yes	Yes	Yes	Yes
2	Cine-like Control Techniques	Pan and Zoom, Frame Rate Control, Window and Level Adjustments, Image Inversion	Pan and Zoom, Frame Rate Control, Window and Level Adjustments, Image Inversion	Pan and Zoom, Frame Rate Control, Window and Level Adjustments, Image Inversion	Pan and Zoom, Frame Rate Control, Window and Level Adjustments, Image Inversion
3	Vessel Measurements	Yes, Using NIH Image Software	Yes, Under Proprietary Method	Yes, Under Proprietary Method	Yes, Under Proprietary Method
4	Display Resolution	512x512, 512x1024, and 1024x1024 Pixels	512x512 and 512x1024 Pixels	512x512, 512x1024, and 1024x1024 Pixels	512x512, 512x1024, and 1024x1024 Pixels
5	Image Enhancement	Real-Time Digital Edge Enhancement While Displaying	Real-Time Digital Edge Enhancement While Displaying	Real-Time Digital Edge Enhancement While Displaying	Real-Time Digital Edge Enhancement While Displaying
6	Case Storage Technique	As a Single Patient Record	As a Single Patient Record	As a Single Patient Record	As a Single Patient Record
7	Interchange of Cardiac Angiographic Studies	CDR DICOM 3.0 Formatted Disk	CDR DICOM 3.0 Formatted Disk	CDR DICOM 3.0 Formatted Disk	CDR DICOM 3.0 Formatted Disk
8	Network Link	Digital Fiber	Digital Fiber	None (Dual-Path Digital Optical Disk as Input to all Review Stations and Archives)	Digital Fiber
9	Image Acquisition into System	DICOM 3 Formatted CDR Disk	CDR DICOM 3.0 Formatted Disk and Analog Acquisition From Cath Lab Camera	Analog Acquisition From Cath Lab Camera	CDR DICOM 3.0 Formatted Disk and Analog Acquisition From Cath Lab Camera
10	Demographics-Based Case Selection Menu	Yes	Yes	Yes	Yes
11	Archive Storage Format	Digital	Digital	Digital	Digital
12	Selected Frames Separately Stored for Use in Report Generation	Yes	Yes	Yes	Yes