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510(K) SUMMARY OF SAFETY AND EFFECTIVENESS

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Device Trade Name: Hewlett-Packard Model M1264B Cathstation
Device Common Name: HP Cathstation (Cardiac Catheterization Recording System)

Classification Name: The following classifications apply to the HP Cathstation (the last classification listed is the only new classification as a result of this modification):

Panel	21 CFR Section	Procode	Description	Tier
74 CV	870.1110	DSK	Blood Pressure Computer	2
74 CV	870.2450	DXJ	Medical Cathode-Ray Tube Display	2
74 CV	870.2810	DSF	Paper Chart Recorder	2
74 CV	870.2300	DRT	Cardiac Monitor	2
74 CV	870.2340	DPS	Electrocardiograph	2
74 CV	870.2350	DRW	ECG Lead Switching Adapter	2
74 CV	870.2050	DRR	Biopotential Amplifier and Signal Conditioner	2
74 CV	870.2060	DRQ	Transducer Signal Amplifier and Conditioner	2
73 AN	870.2700	DQA	Oximeter	2
74CV	*870.1130*	*JOE*	*Noninvasive Blood Pressure Measurement System*	*2*

Predicate Device: For the HP Cathstation modification described in this 510(k) submission, the legally marketed devices to which we claim equivalence is the HP M1008B Noninvasive Blood Pressure module (K903771) used with the HP Component Monitoring System.

Device Description: The HP Cathstation is modified by the addition of the HP M1008B Noninvasive Blood Pressure (NBP) plug-in module for display and recording of NBP numerics on the HP Cathstation.

Intended Use: As for the current HP Cathstation, the added NBP module is intended for use in the cardiac cath lab on adult, pediatric, and neonatal patients undergoing cardiac cath procedures. The intended use for the HP Cathstation NBP module is the same as the intended use for the legally marketed predicate device and several other products currently on the market. Other

aspects of this modification are also consistent with the predicate device. This modification adds established NBP measurement and reporting capabilities to the HP Cathstation, providing additional information to clinicians in the cath lab.

Technological Characteristics: The NBP plug-in module for the HP Cathstation has the same technological characteristics in acquiring NBP signals and computing and displaying NBP numerics as the legally marketed predicate device.

Description statements were not relied on alone to show substantial equivalence to legally marketed devices; instead, performance data from device validation is used as well. The comparison of intended use and technological features of this modification to the legally marketed predicate device taken together with the validation results and other information in this submission indicate that this modification is substantially equivalent to the legally marketed predicate device with regards to safety, effectiveness and intended use.

The safety of this modification is shown by compliance to relevant safety standards for medical devices, such as IEC 601 and UL 2601. Software safety is verified by hazard analysis and software validation to ensure the product performs as intended. Performance specifications for this modification have been validated.