[510(K)] SUMMARY OF SAFETY AND EFFECTIVENESS

The M1205A OmniCare Component Monitoring System is intended for monitoring, recording, and alarming of multiple physiological parameters for adult, neonatal and pediatric patients in the hospital environment. There was no change to the intended use statement.

HP M1205A OmniCare Component Monitoring System Rev. E (Rev. D is not used for this product) is a modification of OmniCare Model 24 Rev. C. Modification of the device was limited to three of 29 functional blocks of software that comprise the OmniCare Model 24 Product (originally cleared under K950821). Changes to the OmniCare Model 24 device software were confined to the ECG/ Respiration, CO_2 and SpO_2/PLETH functional blocks. Modification was accomplished by reusing and leveraging software originally developed for CMS Rev. D (K941811). No new software was designed for this device. For that reason, the modification and this notification are nearly identical to that of the previously modified CMS device.

OmniCare Model 24 was thoroughly validated in R&D and in the SQE department.

Description statements were not relied on alone to assure 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 the modifications of this device to another legally marketed device taken together with the validation results and other information in this submission indicate that this device is substantially equivalent to legally marketed predicate devices in safety, effectiveness and intended use.