CERNER®

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510(k) Statement

I certify that, in my capacity as Director, Regulatory Affairs at Cerner Corporation, I will make available all information included in this traditional premarket notification on safety and effectiveness within 30 days of request by any person if the device described in the premarket notification submission is determined to be substantially equivalent. The information I agree to make available will be a duplicate of the traditional premarket notification submission, including any adverse safety and effectiveness information, but excluding all patient identifiers, and trade secret and confidential commercial information, as defined in 21 CFR 20.61.

Shelley S. Looby
Director, Regulatory Affairs/Quality Assurance
Cerner Corporation