



510(k) Statement	Number: FDA04 Attachment G
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I certify that, in my capacity as the manager of Quality Assurance and Regulatory Affairs of Pel-Freez Clinical Systems, LLC, I will make available all information included in this premarket notification on safety and effectiveness within 30 days of request by any person if the device is found to be substantially equivalent. The information I agree to make available will be a duplicate of the premarket notification, including any adverse safety and effectiveness information, but excluding all patient identifiers and trade secret and confidential commercial information as defined in 21 C.F.R. § 20.61.

Date: 3/17/00

Name: Brian Loeffler
Brian Loeffler
Manager of Quality Assurance
and Regulatory Affairs