510(k) STATEMENT
of
SAFETY and EFFECTIVENESS

[As required by 21 CFR 807.93]

I certify that, in my capacity as Managing Director of Viamed Ltd, I will make available all information included in this pre-market notification on safety and effectiveness within 30 days of request, by any person, if the device described in the pre-market notification is determined to be substantially equivalent.

The information I agree to make available will be a duplicate of the pre-market notification submission, including any adverse safety and effectiveness information, but excluding any patient identifiers, and trade secret and confidential commercial information, as defined in 21CFR 20.61.

(Signature)

John S. Lamb
(Typed Name)

(Date)

Pre-market Notification [510(k)] Number: