INTERNATIONAL Clement Clarke
A HAAG-STREIT COMPANY

K962074

APPENDIX 1

JAN -2 1997

PRE-MARKET NOTIFICATION CERTIFICATION AND SUMMARY

I certify that I have conducted a reasonable search of all information known or otherwise available to me about the types and causes of safety and/or effectiveness problems that have been reported for the **VMX MINI-LOG FLOWMETER, VENTILOMETER VM1 and VM PLUS.** I further certify that I am aware of the types of problems to which the **VMX MINI-LOG FLOWMETER, VENTILOMETER VM1 AND VM PLUS** is susceptible and that the following summary of the types and causes of safety and/or effectiveness problems about the **VMX MINI-LOG FLOWMETER, VENTILOMETER VM1 and VM PLUS** is complete and accurate:

1. **Safety Problems**

a) No safety problems should be experienced during use of the device for its intended purpose, and none have been reported for either the **VMX, VM1 or VM PLUS.** The device complies fully with International BS EN 1SO 60601-1 Standard **"MEDICAL ELECTRICAL EQUIPMENT; GENERAL SAFETY REQUIREMENTS".**

b) General Medical Standards of cleanliness should be observed in maintaining the instrument, and the mouthpiece should be routinely sterilised in accordance with the Users Instructions.

2. **Effectiveness Problems**

Low battery power will prevent use of the instrument, but visual indication of this is shown on the instrument display, allowing time for a replacement to be fitted.

- **PRINTED NAME OF PERSON REQUIRED TO SUBMIT 510 (K)**

.....M.J. WILKINSON.....

- **SIGNATURE OF PERSON REQUIRED TO SUBMIT 510 (K)**

.....

- **TITLE OF PERSON SUBMITTING 510 (K)**

.....QUALITY ASSURANCE MANAGER .....

- **NAME OF COMPANY : CLEMENT CLARKE INTERNATIONAL LIMITED**

- **DATE:** 10 May 1996