Attention:
Application Examiner

Re: Request for confidentiality

Applicant: Radi Medical Systems AB

FCC ID: U4L01080410

To whom it may concern,

Permanent Confidentiality

Request is hereby submitted by Radi Medical Systems AB to withhold permanently from public review certain portions of the application for equipment certification for the referenced FCC identifiers. This request for confidentiality is made pursuant to 47 CFR 0.457(d) and 0.459 of the FCC Rules. In particular, the following sections of the application are to be kept permanently confidential:

- Schematics
- Detailed Block diagrams
- Detailed Operational/Functional Description
- Parts list
- Internal photos (only when new technology is involved ; requires additional justification)

Additional justifications:

Internal photos: The internal photos of the transmitter, FCC ID: U4L01080410, which is part of the medical device PressureWire® Aeris, uses Radio-frequency Wireless Technology which is considered new technology in this application.

Short-term Confidentiality

Request is hereby submitted by Radi Medical Systems AB to withhold from public review for a period of 45 days from the date of the Grant of Equipment Authorization and prior to marketing, certain portions of the application for equipment certification for the referenced FCC identifiers. This request for confidentiality is made pursuant to 47 CFR 0.457(d) of the FCC Rules. In particular, the following sections of the application are to be kept confidential for a period of 45 days from the date of Authorization:

- Test setup photos
- External photos
- User manual

User manual: As the transmitter is a component of PressureWire® Aeris the Instructions for Use is covering not only the use of the transmitter but also all procedures for the use of the Medical equipment PressureWire® Aeris. The Instruction for Use for Medical devices requiring 510(k) from FDA is confidential until 510(k) is achieved.

Rationale for request for confidentiality:

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Radi Medical Systems AB has invested considerable time and materials in research and development to produce the referenced product.
Disclosure of the permanently confidential portions of this application to competitors would not only give them significant competitive advantages in developing similar products, but would also disclose successful implementation of unpublished, leading edge technology developed by us.
Disclosure of the short-term confidential portions of this application during the period of importation and/or distribution would reveal key aspects of proprietary technology to competitors and diminish the value of our investment in research and development.

Furthermore, the transmitter, FCC ID: U4L01080410, is part of the PressureWire® model Aeris which has not got 510(k) from FDA yet. Consequently all documentation regarding the product is not allowed to be available in the US until 510(k) is achieved. 510(k) can be achieved at the earliest 90 days from the date submitted to FDA. The plan is to submit all documentation to FDA February-March in 2008.

If you have questions or need further information, please contact the undersigned.

Sincerely,

Björn Palmgren
Regulatory Affairs Officer
Radi Medical Systems AB

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