Renishaw plc
New Mills, Wotton-under-Edge,
Gloucestershire GL12 8JR
United Kingdom

Tel +44 (0) 1453 524524
Fax +44 (0) 1453 524901
Email uk@renishaw.com

www.renishaw.com

RENISHAW
apply innovation™

1st February 2006

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, rm. 1061
Rockville, MD 20852
USA

Dear Sir or Madam,

Subject: Application for Variance – Laser Notice 50 Modified Statement of Compliance

We wish to apply for a variance to the certification label requirements defined in Laser Notice 50 for our RSP2 probe product.

The following information is that required by CFR 21 Part 1010.4 Variances.

i) Description of Product and its intended Use.

The RSP2 product is a measurement probe for attachment to a Co-ordinate Measuring Machine (CMM) commonly used in industry for the precise measurement of manufactured parts.

ii) An explanation of how compliance with the applicable standard would restrict or be inappropriate for this intended use

It would be impractical to mark, label or tag the product with the modified statement of compliance required by Laser Notice 50 due to its small size. The necessary font size would make any labelling or marking directly applied to the product difficult or impossible to read.

Any tags attached to the product could affect the accuracy of measurement, restrict the access of the RSP2 probe into parts to be measured or catch and become hazardous as the probe is moved around the CMM.

iii) A description of the manner in which it is proposed to deviate from the requirement

Our proposal is that the product is marked with the wording "Complies with FDA requirements. See user Guide" and that a statement containing the full wording of the modified statement of compliance according to Laser Notice 50 is contained within the User Guide which accompanies the product.

The statement of compliance will be in a prominent section at the front of the user guide that also contains statements of compliance with relevant European Legislation (CE marking) and FCC requirements for electromagnetic compatibility.

iv) A description of the advantages to be derived from such a deviation

We believe the proposal will provide a clear and practical way of informing the user of compliance with relevant standards.

v) An explanation of how alternative or suitable means of radiation protection will be provided.

Not applicable.

INVESTOR IN PEOPLE

vi) The period of time it is desired that the variance be in effect, and, if appropriate, the number of units the applicant wishes to manufacture.

For the life of the product. Typically 15 years.

vii) In the case of prototype or experimental equipment, the proposed location of each unit.

Not applicable.

viii) Such other information required by regulation or by the Director, Centre for Devices and Radiological Health, to evaluate and act on the application.

Not applicable.

ix) With Respect to each nonclinical laboratory study .....

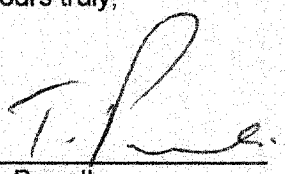
Not applicable.

xi) If the electronic product is used in a clinical investigation involving human subjects....

Not Applicable.

I trust that the above information adequately describes our application for a variance and look forward to your reply.

Yours truly,



T. Powell
Senior Project Engineer
CMM Products Division

Direct Tel +44 1453 524911
e-mail tim.powell@renishaw.com