Oridion

ד"בס

Docket Movement Branch (HFA-305)
Food and Drug Administration
5630 Fisher Lane Rm. 1061
Rockville, MD 20852
USA

Re: Docket No. 03D-0063

Medical Devices: Guidance for
Industry and FDA: Fiscal Year 2003
Medical Device User Fee and
Modernization Act of 2002 Small
Business Qualification Worksheet and
Certification; Availability

Dear Sirs:
This guidance requires that the business entity requesting to be classified as a small business submit a copy of their US Federal **Income tax Form. We are a small business located in Israel and do** not file a US Federal income tax form. If this is not corrected then **small businesses located outside the USA will be unable to request** this waiver. In 2001 we requested and were granted a small business **waiver of submission fee for our first NDA. We submitted appropriate** financial data that was accepted by the FDA. This guidance should be **amended to cover the case of non US device companies.**

Mr. Sandy Brown
Regulatory Affairs Director
Oridion Medical 1987 Ltd.
POB 45025
91450 Jerusalem, Israel
TEL: +972-2-589-9115
FAX:+972-2-586-6680
email:sandy.brown@oridion.com

03D-0063 C 1