Microstim Supramaximal stimulator

Benefits of the Device against residual risks

The Microstim was originally designed by a team in the Medical Physics department of MRI circa 1985. At that time CE marking did not exist and ISO900 (BS5750) was not in operation
Clinical trials were not standardised or officially formatted so were carried out in vitro with hospital consultants. Validation was carried out by comparisons with existing competitors instruments.
The technolgy and its uses were new and developing so the product evolved from the original Microstim MS1000 to its present day format. The clinical requirements and the longevity of the product prove efficacy of design and manufacture over 30 years. There are only two residual risks I.e innacurate diagnosis from the results and mis use by untrained operators. Neither of these is harmful and the main risk is to give a painful very short term electric shock to the patient.
The possible effect on pacemakers has been know since the early days and warning is given in the manual. This product is not unique and has a range of competitors.

"Clinical evaluation of Microstim " is submitted as a comprehensive list of the documentation used in the technical file.
Post market surveillance document Doc 16770 16/04/16 by D lamb
Clinical papers Doc 15596 By J.S.Lamb
Checked by J.S.Lamb.
No negative results were found.
This device residual risk if far outweighed by its efficacy and reliability displayed over 30 years

John S Lamb.

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