Products without Clinical Trial Data Product

The Microstim MS1000,: DB: DBII:DBIII have not been subjected to Clinical trials as defined in Annexe 10 and the Microstim MS1000 & DB have been placed on the market prior to the introduction of the CE mark and associated procedures
They were subject to clinical trials on an ad hoc basis by Dr Nigel Harper in Manchester Royal Infirmary operating theatres

Placed on the market prior to 1988	YES
Grandfather product	YES MS1000: Microstim DB: Microstim DBII: & III
Equivalent to other products on the market	YES A range of competetive products has been introduced since 1986

1. Benefit /risk of the device
   All risks apart from the patient having a pacemaker rest with the operator being trained and competent to use the product. Usage is covered by a comprehensive user manual
2. Equivalence to other devices on the market
   After preliminary work to establish the principles of peripheral nerve stimulation The original Microstim was designed to be a low cost version of contemporary products that started to appear at the same time.
3. Demonstration of acceptability to harmonised standards
   See full CE Technical File
4. The “state of the art”
   The Microstim family has been continually evaluated and modified to incorporate “state of the srt” technology. The mIcrostim MKIII is identical in electronic design to the Microstim DBII but has a new enclosure and patient cable
5. Post market surveillance data on device performance
   Comprehensive records are available logging customer complaints..
6. Vigilance reports
   User observations and product failures have been continually addressed and where possible weak areas have been designed out
7. Registry data
8. Maintenance history
   Full repair history form MS1000 S/N 1 is available and accessible
9. Sales/marketing feedback

This has been incorporated wherever possible throughout the products life.
   Eg, The original enclosures were changed as they were susceptible to damage if dropped
   A patient connect indicator was added
   The unit was upgraded from Train of four to Double burst Stimulation to meet changes in medical procedures
   Components have been periodically changed and upgraded when failure rates revealed them
   Sales have increased substantially with the introduction of the MKIII

10. User feedback.
    User feedback particularly from young anaesthetists in Canada is propelling the current 2009 changes.