CLINICAL EVALUATION REPORT

Compiled by

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Microstim MkIII

1. General details

Microstim MkIII Peripheral nerve stimulator designed for use during anaesthesia.

Manufacturer:

Viamed Ltd
15 Station Road
Cross Hills
Keighley
West Yorkshire
BD20 7DT

2. Description of the device and its intended application.Intended therapeutic and/or diagnostic indications and claims

Muscle relaxants, often used with general anaesthetics during surgery, block neuromuscular transmission (the communication process whereby a nerve impulse produces muscle contractions), and therefore the sensation of feeling.

The Microstim is a peripheral nerve stimulator used to monitor this block by simulating a stimulus from the brain to the muscle.

Any resultant muscle contraction indicates the patient's level of paralysis, the anaesthetist can then evaluate the neuromuscular block (and therefore the sensation of feeling), and take appropriate action.

4. Context of the evaluation and choice of clinical data types.

The Clinic Evaluation has been performed via, Clinical Experience data / documentation and Clinical literature search(s).

Sources of data/documentation used in clinical evaluation.

Review of Essential requirements Current DOCID 15722

Review Risk Assessment current DOCID 19657

Risk against Benefits DOCID 16895

Post-market Surveillance report:

Section 1 Stock Identification

Section 2 Supplier Review

Section 3 Sales Review

Section 4 Countries Review

Section 5 Returns / Services Review

Section 6 Design Changes Review

Section 7 IFU Review

Section 8 Labels Review

Section 9 Documentation updates Review

Section 10 Internal Issues Review

Section 11 Clinical Data / FDA Incidents Search

Current DOCID 19655

All returns / failure records since 2001 are computerized and reviewed annually.

See post market surveillance reports DOCID 19655.

There have been no recalls of Microstim units.

All units have Q.A. Records and service records indicating the devices perform as intended.

Sales / Returns and service logs data See DOCID 19655

Microstim units have been on the Market since 1990's. There have been no signification design changes in 10-20 years..

5. Summary of the clinical data and appraisal

As there have been no clinical trials carried out on behalf of Viamed, this report is based on literature search . Technical File “Microstim“

As Per Annex X CLINICAL EVALUATION

1.1d Where demonstration of conformity with essential requirements based on clinical data is not deemed appropriate, adequate justification for any such exclusion has to be given based on risk

management output and under consideration of the specifics of the device/body interaction, the clinical performances intended and the claims of the manufacturer. Adequacy of demonstration of conformity with the essential requirements by performance evaluation, bench testing and pre-clinical evaluation alone has to be duly substantiated.