CLINICAL EVALUATION REPORT

Compiled by

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Microstim III

General details

Tom Thumb Resuscitator

Part Numbers: See DOCID 16770

Manufacturer:

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

Description of the device and its intended application.

To assess the depth of neuromuscular blockade, ensure proper dosing, and minimize side effects when neuromuscular blocking agents (NMBAs) are used.

Intended therapeutic and/or diagnostic indications and claims

Neuromuscular Blocking Agents (NMBA)s – Drugs classified as neuromuscular blocking agents that are given to block musculoskeletal activity resulting in paralysis. These agents can be nondepolarizing and depolarizing in nature.

Supramaximal Stimulation (SMS) – The level at which additional stimulating current elicits no further increase in the intensity of the four peripheral nerve twitches. This is a baseline determination that helps establish adequate stimulating current and improves reliability of testing.

Train of Four (TOF) – Used to describe the pattern of electrical nerve stimulation and evaluate the degree of neuromuscular blockade. After delivery of four successive stimulating currents to a select peripheral nerve with the peripheral nerve stimulator (PNS), the number of twitches correlates with the degree of neuromuscular blockade.

Conditions to treat

Context of the evaluation and choice of clinical data types.

Annex X 1.1d.

Sources of data/documentation used in clinical evaluation evidence.

Review of Essential requirements Current DOCID 15722

Review Risk Assessment current DOCID 16772

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 16770

Benefits of MicroStim against residual risks report DOCID ???

All returns / failure records since 2006/2007 are computerized and reviewed annually.

See post market surveillance reports DOCID 16770.

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 16770

Microstim units have been on the Market since before 1990 (documented proof back to 1990 DOCID 17413) There have been no design changes in 8 years.

Technology:

Demonstrating safety and performance via data records (Annex X 1.1d) .

Microstim units have been on the market since 1990,

Very low number of failures as shown DOCID 17415.

complaints and vigilance data.

There have been no customer complaints regarding the functionality of the device.

There have been zero vigilance reports / MHRA complaints.

Product Changes

There have been limited changes, introduction of ROSH, forcing the changing of components, in 2005 a Case redesign.

In 2008 a Special function version was produced for Dyna Medical.

Conclusion

With 26+ years on the market the device has proved itself to be fundamentally a safe device and as the example records from DOCID 17415 the Microstim has proved itself to be reliable.

Information on author

John S. Lamb
Educated at;-
Heaton Grammar school 1953-1958
Sunderland Polytechnic (now Sunderland university) HNC Applied Physics.
1962 – 1965 Radiotherapy(Medical Physics) Design development and repair of medical electronic equipment.
From 1965 and through the 1970's medical equipment began to expand into specialist areas.
Many original products were developed and manufactured in this period requiring a general overall understanding of medical equipment, the medical environment and medical procedures.
Many current products and procedures were introduced tested and improved without formal clinical trails or standards . The time period between design and subsequent use could be measured in days.
It became import very early on to work closely with the then DHSS and to apply a high standard of manufacture and quality control. Many of these applications were incorporated in the medical requirements which eventually formed the current CE system.
The current Viamed manufactured products were designed , developed and manufactured in the early 1980's so although original design information is still available no formal clinical trials were carried out.
On the publication of BS5750 Viamed achieved ISO in 1993 one of the first small ISO medical companies. This was no small achievement for a company of about 12 people.
From there we have consistently progressed to the current position.
Throughout the period of Viamed 1977- we have consistently returned extremely low numbers of both complaints and MHRA correspondence. Products are proved reliable by the low number of failures and continuous sales.

John S. Lamb
26/08/2016

NOTE
* Lotus Approach requires older Microsoft OS. Will it will function and open in the latest version windows 10. It crashs when attempting to Print. So the