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FEB 4 2008

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510(k) Summary

5.1 Document Details

The owner of the 510(k) is Musmate Ltd. Musmate Ltd is a company registered in England & Wales, Number 5671724.

- The registered office of the company is at 124 High Street, Midsomer Norton, Somerset BA3 2DA, United Kingdom.
- The company operates from the following address: 4 Ford Road, Peasedown St John, Bath, BA2 8DG, United Kingdom.
- The company uses the postal address P.O. Box 3976, Bath, Somerset BA1 0DF, United Kingdom.

- The company's telephone number is +44-(0)845-094 4674
- The company's fax number is +44-(0)845-094 4674
- The company's e-mail address is musmate@uk2.net.

The official contact person is Dr Andrew James Wynd, who is the company director.

The company is not yet registered with the FDA., but will do so once clearance is obtained.

This summary was prepared on 29th November 2007

5.2 Product Details

- Trade name – Musmate
- Common name- foot drop brace
- Classification name- Limb Orthosis (21 CFR 890.3475)

The Musmate uses six out of eight components, depending on whether it is for a single leg or both legs.

- A shoulder harness for a single leg (left or right) which holds the elastic assembly in place and is available in two mirror-image designs (for the left leg and for the right leg), four sizes, and a range of colours. It is made from polypropylene webbing and plastic components. There are adjusters to alter the length of the harness to suit the individual. It has a length-adjusting strap which controls the height of the foot lift. This has a triangle on one end which connects to the upper hook on the elastic cord assembly, and a square ring grip which the person pulls on to adjust. The strap passes through a ladderloc control which prevents the strap moving in use. The shoulder harness has two front release clips which connect to the waist belt (or which can be clipped together if the belt is not used);

- An optional waist belt made from polypropylene webbing. This features two adjusters so that it is adjustable in length to suit each person and clips for attaching to the shoulder harness. This is available in three lengths and a range of colours;

- A shoulder harness for both legs. This is made from polypropylene webbing. Its function is to hold the elastic assembly in place and it is available in one design, four sizes, and a range of colours. This features triglide adjusters to alter the length of the harness to suit the individual. There is a steel ring on the rear which brings the different parts together. It has a length-adjusting strap which controls the height of the foot lift. This has a triangle on one end which connects to the upper hook on the elastic cord assembly, and a square ring grip

which the person pulls on to adjust. The strap passes through a ladderloc control which prevents the strap moving in use. The shoulder harness has two front release clips which connect to the waist belt (or which can be clipped together if the belt is not used);

- Optional polypropylene webbing waist half-belts for the shoulder harness for both legs which help balance the harness if the loads applied are different on each leg. Two are used out of the four supplied (there are two short and two long). These feature an adjuster so that it is adjustable in length to suit each person. There are two front release clips which connect to the shoulder harness. These are available in six lengths and a range of colours;

- An optional foam shoulder pad which can be used to cushion the load of the shoulder harness until the muscles become accustomed to the additional effort. This is made from leatherette with a foam insert and hook and loop fastenings. It is available in two sizes and a range of colours;

- An elastic cord assembly. This is made from 8mm shock cord, which has a rubber core and polypropylene sheathing. It has a nylon peg adjuster which can be used to adjust the elastic cord for length to optimise the support offered by the Musmate. There is a hook at the top for connecting to the shoulder harness, and one at the bottom for connecting to either the shoe harness or shoelace connector as required. The cord is only available in black, and the nylon adjuster and hooks are available in black and white;

- A shoe harness made from shoe soling which wraps under and over the shoe. This is secured with hook and loop fittings. There is a polypropylene strap which is sewn onto this which goes around the back of the shoe to hold it in place. This is adjustable in length with a triglide adjuster. This also has a front-release clip for ease of removal, and a short length of elastic tape for tensioning the harness on the shoe. There is a triangle on top of the shoe which is used to

connect to the elastic cord assembly. The position of the triangle which connects to the elastic cord assembly can be adjusted to suit the person's requirements;

- A shoelace connector which goes round either shoelaces or a sandal strap for a discreet but secure fit. This is made from polypropylene webbing with a plastic triangle and a front release clip.

The Musmate works in the following manner. When you place your foot on the ground during the gait cycle, you stretch the elastic cord. Then, when you lift your leg to walk forward, the shoulder harness acts as an anchor, the tension on the cord is reduced by the lifting of the leg and so contracts. This lifts your foot up. The length of the elastic cord is adjustable so that the amount of support is altered to best meet your needs. A shorter cord has a stronger action, because it has to be stretched further to reach the ground and also because more of the elastic cord is doubled over by the adjusting nylon peg. The height of the foot lift is adjustable by changing the length of the length-adjusting strap on the shoulder harness. A shorter strap will lead to a higher lift because the effective end of the elastic cord assembly is raised higher up.

The person using the Musmate puts the shoulder harness, shoulder pad (if used), and waist belt on first. They then attach the desired shoe harness or shoelace connector onto their shoes and then connect the two with the elastic cord assembly. They stand up and then adjust the tension in the elastic cord to their satisfaction.

5.3 Predicate Device

890.3475 KNP Foot-up orthotic device

5.4 Intended Use Comparison

This is summarised in the following Table.

Table 5.1 Functional Indication Comparison

Device	**Foot-Up**	**Musmate**
Anatomical Sites	Foot	Foot
Function	The Foot-Up is a lightweight dynamic aid for drop foot or related disorders which require dorsal flexion support.	The Musmate is a dynamic aid for drop foot or similar disorders who have a lack of ankle dorsiflexion.
Indications	The Foot-Up is indicated for foot-raising paresis, particularly suitable for KG 3,4	The Musmate is indicated for foot-raising paresis.
Contra-indications	(i) circulatory disorders (ii) neurogenically-specific organoleptic and skin trophic disorders in the body area being treated (sensory disorders with and without skin damage)	Due to the additional effort, people with weak backs (eg from arthritis of the spine) should not use the Musmate. It supports walking and so those who are unable to walk 10 metres (with aids such as walking sticks) may not benefit without appropriate professional medical support.
Side-effects	With proper use and proper fitting, so far there have been no reports of serious general side-effects. Local pressure symptoms and impaired circulation can be prevented with sufficient certainty on an individual basis if allowance is made for any contraindications and with non-restricting consistently-shaped body fitting.	May cause temporary leg, knee, shoulder, and/ or back pain. There has been one report of pins and needles in the feet following use.
Cautions	None	Check shoes regularly for wear and tear. The Musmate cannot be used with some shoes such as high heeled or low-cut shoes, or those which have no heel (eg clogs). The Musmate may lead to additional wear and tear or scuffing on clothes and shoes.

5.5 Technological Comparison

The following Table 5.2 summarises the technological characteristics of the Musmate and the predicate device, the Foot-Up.

Table 5.2 Technological Comparison of the Foot-Up and Musmate

Device	Foot-Up	Musmate
Duration of Use	Designed to be worn continuously to provide foot-raising support	Designed to be worn continuously to provide foot-raising support
Core Technology	Support provided by elastic strap	Support provided by elastic cord
Anchor Point	For the product on the left foot: the left ankle For the product on the right foot: the right ankle	For the product for the left foot: the right shoulder For the product for the right foot: the left shoulder For the product for both feet: both shoulders
Foot Connecting Components	(i) A shoelace connector which has an insert which locates between the tongue of the shoe and the shoelaces, with the elastic cloth rising between shoelaces to join to the ankle.	(i) A shoelace connector which passes round shoelaces or sandal straps and has a triangle to connect to hook on the elastic cord. (ii) A shoe harness which goes around the shoe and can therefore be used on shoes without laces.

5.6 Clinical Test Data Summary

When the test started, the mean walking speed of the group was 0.44ms^{-1}, which rose to 0.64ms^{-1} when the Musmate was initially fitted. The T-Test result was 6.194 with a 2-tailed significance of 0.000. After one month, the walking speed without the Musmate had increased to a mean 0.57ms^{-1} (T-test 3.371, significance 0.003) and with the Musmate to 0.73ms^{-1} (T-test 2.828, significance 0.013). Comparison of the initial walking speed without the Musmate and the final speed with it, yielded a difference of 0.29 ms^{-1} (T-test 5.795, significance 0.000) .

Table 5.3 The T-Test Values

Device	Mean Difference (Note 1)	Estimated Standard Error	Degrees of Freedom	T-Test	Probability Value
Ankle Foot Orthosis 890.3475 IQI	0.10	0.048	11	2.035	0.067
Ankle Foot Orthosis 890.3475 IQI	5.92	3.360	8	1.762	0.116
Functional Electrical Stimulation 882.5810 GZI (note 2)	0.15	0.046	110	3.285	0.001
Musmate	0.29	0.095	15	3.069	0.008

5.7 Conclusions

The comparison of the clinical factors showed substantial equivalence between the Musmate and the predicate device, the Foot-Up. The technological and design comparison between the Musmate and the predicate device showed that there was substantial equivalence between the Musmate and the Foot-Up. The design differences meant that the Musmate has additional functionality, improved flexibility and overall a lower risk profile than the Foot-Up. Clinical trial data and a literature review demonstrated that the Musmate showed a statistically significant improvement in walking speed and its clinical benefit was as good as, or better than existing treatments. Substantial equivalence is therefore demonstrated.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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FEB 4 2008

Musmate LTD
% Mr. Andrew James Wynd
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Bath, Somerset,
United Kingdom BA2 8Dg

Re: K073521
Trade/Device Name: Musmate Walking Aid
Regulation Number: 21 CFR 890.3475
Regulation Name: Limb orthosis
Regulatory Class: Class I
Product Code: OHI
Dated: December 7, 2007
Received: December 17, 2007

Dear Mr. Wynd:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

We note that your device exceeded the Limitations of exemptions from section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 CFR Part 890.9), and therefore required the submission and clearance of a premarket notification prior to commercial distribution in the United States. Future devices of this same type, that meet the exemption criteria and do not exceed the limitations of exemptions found in 21 CFR Part 890.9 will be exempt from the premarket notification requirements of the Act.

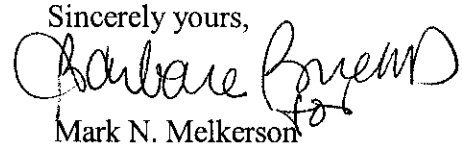
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at toll-free number (800) 638-2041 or (240) 276-3150 or Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,



Mark N. Melkerson
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

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4. Indications for Use Statement

510(k) Number (if known): **K073521**

Device Name: **Musmate Walking Aid**

Indications for Use

Foot raising paresis.

Table 4.1 Summary of Use by Type

Prescription Use		Over-The-Counter Use
___YES____	AND/OR	_YES_____
(Part 21 CFR 801 Subpart D)		(21 CFR 801 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE OF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Barbara Bueno

(Division Sign-Off)
Division of General, Restorative, and Neurological Devices

510(k) Number K073521