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Derek Lamb <liquidgands@gmail.com>

MHRA Ref: 2013/005/020/401/001 - SpiroTrue A flow sensors

4 messages

Emma.Rooke@mhra.gsi.gov.uk <Emma.Rooke@mhra.gsi.gov.uk> 1 August 2013 11:13
Reply-To: Emma.Rooke@mhra.gsi.gov.uk
To: liquidgands@gmail.com

Dear Mr Lamb,

Thank you for your report.

Please could you clarify whether this is a single patient use device or re-useable device. From your report it would appear to be a single patient use device, but the e-mail sent to Mr Williams (who reported this incident) on 13/05/2013 states that they are not single patient use devices. In addition, I cannot see any indication on the instructions for use that these are single use devices rather than re-useable devices.

Please can you also confirm the date that flow sensors made from ABS from the alternative supplier went into production, and the dates that Viamed started and ceased supplying devices manufactured from this alternative material.

Kind regards,
Emma

Emma Rooke
Medical Device Specialist - MHRA
Tel: 0203 080 6609

Date: 31/07/2013 17:04:00

From: liquidgands@gmail.com On Behalf Of
Derek Lamb

ToAIC,

cc

bcc

SubjectFINAL Third Reminder to Manufacturer MHRA
Ref: 2013/005/020/401/001

Attachments: <<*see below*>>

From: liquidgands@gmail.com [mailto:liquidgands@gmail.com] **On Behalf Of** Derek Lamb
Sent: 31 July 2013 17:04

To: AIC
Subject: FINAL Third Reminder to Manufacturer MHRA Ref: 2013/005/020/401/001

Dear Mr Noel Grocia,

Please find attached.

Regards

Derek Lamb

On 30 July 2013 15:27, <Noel.Grocia@mhra.gsi.gov.uk> wrote:

> 30/07/2013
>
> Mr D Lamb
> Viamed Ltd
> 15 Station Road
> Cross Hills
> Keighley
> West Yorkshire
> BD20 7DT
> UK
>
> MHRA Ref. 2013/005/020/401/001
> Your Ref. #43051
>
> Dear Mr D Lamb
>
> We have written to you on three occasions to request that you investigate this incident and inform us of your findings. To date we have received no final report concerning this matter.
>
> Our third letter reminded you that it is the manufacturer/manufacturer's representative's responsibility to ensure that all incidents reported to you, that concern your devices, are investigated appropriately and that your devices are safe for use and comply with the relevant legislation in the UK. It is consistent with the terms of the Medical Devices Directive that the person responsible for placing a device on the market adopts responsibility for adhering to the vigilance system and for Quality

Assurance, including post-market surveillance, risk analysis and trending. In addition, if the manufacturer/manufacturer's representatives intend to apply the exemption criteria described in the latest version of the MEDDEV vigilance guidelines, it is assumed that all incidents involving their devices ill be appropriately documented and trended.

As previously stated, it is the MHRA's responsibility to ensure that medical devices are safe for their intended use. The MHRA endeavours to ensure that every incident requiring investigation is progressed according to the information available. The results of all concluded investigations, even minor ones, are trended by us.

Yours sincerely,

Noel Grocia

pp Mr R Saunders
Head of Adverse Incident Centre, MHRA

PLEASE QUOTE OUR REFERENCE IN ANY REPLY

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1. Any email reply to this correspondence should be addressed to: **aic@mhra.gsi.gov.uk** Replies sent to personal email addresses may be delayed because of staff absence.

2. Do not send medical devices to the MHRA unless you have been specifically requested to do so. If responding to such a request, you must ensure that the device has been appropriately decontaminated, securely packaged, and clearly labelled (including the MHRA reference number)

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Communications via the GSi may be automatically logged, monitored and/or recorded for legal purposes.[attachment "Report for MHRA 310713 MHRA Ref 2013005020401001.pdf" deleted by Emma Rooke/MHRA]

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Derek Lamb <liquidgands@gmail.com> 2 August 2013 15:44
To: Emma.Rooke@mhra.gsi.gov.uk

Sorry yes you are correct my mistake
When we Originally went for the own branding they were classed as single patient use, however after discussions with BSI, and our reasoning for it being classed as single patient use (the product has a limited life span once put into use), was incorrect.
we changed it to a re-usable product but stressed in the instructions the life cycle of the product is limited.

From our manufacture with regard shipments using the Alternate supplier:

Alternative ABS for SpiroTrueA/Flowsensor A is used from 02-2012 to 07-2013.

I have to check internally again the first lot we sent to Viamed used alternative ABS material.

Looking at my records we received 1330 Packs of 5 between 02-2012 and 07-2013
Although we have only received 30 Packs of 5 since 05-2013 while we wait on the new ABS versions.

Regards

Derek Lamb
Viamed Ltd.

[Quoted text hidden]

Report for MHRA 310713 MHRA Ref 2013005020401001 02082013.pdf
1377K

Rooke, Emma <Emma.Rooke@mhra.gsi.gov.uk> 5 August 2013 12:16
To: Derek Lamb <liquidgands@gmail.com>

Good morning Derek,

Thanks for getting back to me. I am concerned that the flow sensors are intended for multiple patient use, but cannot be sterilised or autoclaved. Please can you provide your rationale for this?

Kind regards,
Emma

Emma Rooke
Medical Device Specialist - MHRA
Tel: 0203 080 6609

From: Derek Lamb [mailto:liquidgands@gmail.com]
Sent: 02 August 2013 15:45
To: Rooke, Emma
Subject: Re: MHRA Ref: 2013/005/020/401/001 - SpiroTrue A flow sensors
[Quoted text hidden]

Derek Lamb <liquidgands@gmail.com> 5 August 2013 17:39
To: "Rooke, Emma" <Emma.Rooke@mhra.gsi.gov.uk>

Dear Emma,

As per the instructions the flow sensors:
The sensor can be sterilised with ETO before usage.
Serveral disinfection cycles with ethanol solution of 70%,

When we first submitted the files to BSI for review, we had in the instructions the product was for single patient use, and we had the above cleaning instructions in the ifu.
we were informed that

>> >>b. Flowsensor A: From the comments below it appears that the
>> >>intended use of the sensor is for single patient use. This should be
>> >>clearly stated in the IFU again with information on known
>> characteristics
>> >>and technical factors known to the manufacturer that could pose a risk
>> if
>> >>the device were to be re-used for another patient.
>> >> EC 2007/47 directive 13.6(h),

As the product can be cleaned/disinfected, so would not pose a risk, we decided we should remove the single patient use, but add to the instructions.

" if there is any possibility that the sensor is still contaminated a new sensor must be fitted."

On the subject of batchs of product with the premium ABS and the alternative I have the following updated information from our supplier:

- LOT: 6010101B – 50 Boxes - 29.10.2012 (alternative ABS)
- LOT: 6010111B – 50 Boxes – 29.10.2012 (mixture of premium ABS and alternative ABS are possible)
- LOT: 6011131B -100 Boxes – 06.12.2012 (mixture of premium ABS and alternative ABS are possible)
- SpiroTrue A/ Flowsensor A manufactured from 01/2013 until 31.07.2013 are 100% with alternative ABS

So I now have a complete list of all our customers whom have received an Alternate ABS flow sensor from us.

Regards

Derek Lamb

Viamed Ltd.

[Quoted text hidden]