
From: [I/S]
Sent: 4/14/2022 11:08:10 AM
To: [I/S]
Subject: RE: Advertisement advice- Oxehealth

Flag: Follow up

Hi [I/S]

I'm very well, thank you – hope you are too!

Firstly, just to check my understanding, it's the software ('Vital Signs') which is measuring heart and respiration rates that's certified as a class IIa device? The 'location and activity alerts' relate to movement in the room which is monitored via optical sensors that use algorithms to 'alert' carers to 'potential dangers'. Presumably it's sold as a complete package ('Oxevision'), therefore, I'd have assumed that the patient management system as a whole would be classed as a medical device? But perhaps not – I know patient monitoring systems are complicated and I always struggle getting my head round them!

Regarding advertising; annoyingly, we don't yet have the legislation to allow us to take action against companies making misleading claims about medical devices. There is a section covering claims in the proposed future regulations but these have only just gone through the consultation phase so might be a little while before they're in place (if agreed).

The ASA won't look at this type of advertising material because it's clearly targeted at healthcare professionals. Therefore, I think our only option would be to scrutinise their clinical data in relation to their claims for 'self-harm', although this might depend on whether we consider the claims apply to the system as a whole or just to the 'location and activity alerts' element.

Personally, I interpreted the website as promoting one complete system ('Oxevision') so by including 'self-harm' under 'Applications', I believe it is a statement of the product's intended use; that the device can be used to reduce incidents of self-harm. If that's the case, they must have sufficient clinical evidence to support this claim.

I note Oxehealth are registered with us for 'Near infrared camera vital sign measurement software' (class IIa). The registration refers to a clinical investigation - CI/2017/0044. Might be worth speaking to our Clinical team, if you haven't already?

Not sure if that's helpful at all, but do let me know if I can help with anything else or indeed, if I've misunderstood anything.

Best regards,

[I/S]

Lead Compliance Investigator
Devices Compliance Unit

[I/S]

Please note my normal working days are Monday - Thursday

From: [I/S]
Sent: 13 April 2022 17:40

To: [I/S]

Subject: Advertisement advice- Oxehealth

Hi [I/S]

Hope you are well.

I would appreciate your thoughts on this company I have been engaging with due to claims they have made on their website which we believe has a medical purpose. Just a quick background, Oxehealth is a patient monitoring system which includes a vital signs module which is a class IIa medical device. It is a fixed-installation device for use within mental health hospitals. They previously had on their website that it reduces self-harm however, I pointed out to them that the claim has a medical purpose and there is risk that patients and users might think that the system will be able to alert staff to any self-harm attempts. They have now edited their material and removed "reduce". However, the wording "self-harm" is still on their website. Please see below a link to their website:

<https://www.oxehealth.com/applications/self-harm>

They also have on their website % claims which refers to "Staff reported that Oxevision enabled them to prevent incidents of self-harm from occurring (Acute unit)". They have sent the evidence and have also said this will be made available on their website. However, it seems that they have evidence to support the reducing self-harm claim but they are not advertising this to be a software product or software service that Oxehealth has produced. This is very misleading and wanted some advice on how to approach this from an advertisement angle. I hope this made sense and if you need any further information please let me know.

Many thanks,

[I/S]

Senior Medical Device Specialist – Software, Apps and AI

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