Gmail

Derek Lamb <liquidgands@gmail.com>

Re: MHRA Adverse Incident Report - Maxtec EyeMax 2 (Premie)

1 message

Steve Nixon <office@viamed.co.uk> 29 January 2020 at 17:02
Reply-To: steve.nixon@viamed.co.uk
To: Bob Kalish <bkalish@maxtec.com>
Cc: Derek Lamb <derek.lamb@viamed.co.uk>, Steve Hardaker <steve.hardaker@viamed.co.uk>

Hi Bob

Likewise, especially when it concerns a clinical incident.

On the flip side over the past 14 years a good number of EyeMax have been sold and used on a regular basis, so the product quality and design has been well proven and documented..

Steve

On Wed, 29 Jan 2020 at 16:54, Bob Kalish <bkalish@maxtec.com> wrote:

> Hi Steve,
>
> I hate to hear about something like this. I have copied our regulatory folks on this email to respond accordingly.

Bob Kalish
OEM and International Sales Director

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How did I do today?

> On Wed, Jan 29, 2020 at 11:16 AM Steve Nixon <office@viamed.co.uk> wrote:
>
> > MHRA Adverse Incident Report - Maxtec EyeMax 2 (Premie)
> >
> > Hi Bob
> >
> > Can you please provide feedback and advice from Maxtec regarding the attached adverse incident report received from the MHRA. We have just learned of this and we need to construct a response ASAP either from Maxtec or from Viamed (on behalf of Maxtec).
> >
> > Initial quick thoughts:
> >
> > a) Did they affix the EyeMax 2 in accordance with the instructions?
> > b) Did they used the correct size EyeMax 2, did they measure the occipital-frontal circumference? What was the documented occipital-frontal circumference?
> > c) Was the EyeMax 2 overstretched at any time?
> > d) Was the EyeMax 2 used on a single patient? How long had the EyeMax 2 been in use on the patient concerned?
> > e) At the time of the reported incident, how often was the position of the EyeMax 2 checked?
> >
> > Regards
> >
> > --
> > Steve
> >
> > Steve Nixon
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Steve

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