



Device Incident Report 23483 - Eska Implants

to:

04/06/2011 12:45 AM

Cc:

Hide Details

From:

To:

Cc:

Dear

I am writing from Orthodynamics GmbH with regard to the above incident.

In April 2010, The Summit Medical Group acquired the assets of Eska Implants AG and formed the new business of Orthodynamics GmbH. I am therefore carrying out the incident investigation alongside our Australian sponsors ESKA Australia.

Unfortunately, there is now a holiday period in Germany which means that I am not able to submit the full results of our investigation today as planned. However, I will be in a position to submit all of the documents on Monday, which means they will be with you on Tuesday morning.

Please accept my apologies for this inconvenience.

Kind regards,

Leiter Qualitätsmanagement und Regulatory Affairs – Implantate
Quality Management and Regulatory Affairs Manager – Implants

Orthodynamics GmbH
Grapengießerstraße 34
23556 Lüneburg
Germany

Telefon:
Mobil:
Fax:
E-Mail:
Internet:

Sitz der Gesellschaft: Lübeck | Amtsgericht Lübeck HRB 10091 | USt.-Id.-Nr.: DE 815 171 654
Geschäftsführung: Frank Collins, Darren Gates, Ralf Okonnek

Für mehr Informationen besuchen Sie bitte...

Orthodynamics Ltd. 10 Airfield Road
Christchurch, Dorset, BH23 3TG, UK

Telefon: [REDACTED]

Fax: [REDACTED]

E-Mail: info@orthodynamics.co.uk

Internet: www.orthodynamics.co.uk

Summit Medical Ltd. Industrial Park, Bourton on
the Water, Gloucestershire, GL54 2HQ, UK

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To: [REDACTED]
Cc: [REDACTED]
Bcc: [REDACTED]
Subject: Re: DIR 23483 [SEC=UNCLASSIFIED]

Dear [REDACTED]

An extension is granted for the information required of an additional five days. Please fill out the questionnaire with as much information as possible and provide a date in section 10 that the manufacturer believes their investigation/ analysis will be ready for review

The information is now due on 3 June 2011

Kind regards

[REDACTED]
IRIS Coordinator - Device Vigilance & Monitoring |Office of Product Review |Therapeutic Goods Administration

[REDACTED]
<http://www.tga.gov.au>

Post: PO Box 100, Woden, ACT 2606 | Courier: 136 Narrabundah Lane, Symonston, ACT 2609

[REDACTED] Dear [REDACTED] Thank you for your email

24/05/2011 09:57:11 AM

From: [REDACTED]
To: [REDACTED]
Date: 24/05/2011 09:57 AM
Subject: Re: DIR 23483 [SEC=UNCLASSIFIED]

Dear [REDACTED]

Thank you for your email

My company protocol is that I send any request from the TGA to the mother company in Germany

The company in Germany have requested an extension! Is this possible?

Kind Regards
[REDACTED]

On 20/05/11 9:47 AM [REDACTED] wrote:

Dear [REDACTED]

Please attached letter

Also note that further information regarding the reporting of adverse events and the sponsors responsibilities for placing devices on the ARTG can be found at:

<http://www.tga.gov.au/industry/devices-argmd.htm> <
<http://www.tga.gov.au/industry/devices-argmd.htm>>

<http://www.tga.gov.au/industry/devices.htm> <
<http://www.tga.gov.au/industry/devices.htm>>

Kind regards

[REDACTED]
IRIS Coordinator - Device Vigilance & Monitoring | Office of Product Review
| Therapeutic Goods Administration

[REDACTED] url:

www.tga.gov.au <<http://www.tga.gov.au>/>

Post: PO Box 100, Woden, ACT 2606 | Courier: 136 Narrabundah Lane,
Symonston, ACT 2609

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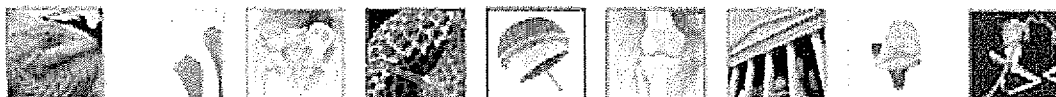
Regards,



72 South Street Rydalmere New South Wales 2116 Australia | Mob: [REDACTED] | [REDACTED]

Tel: [REDACTED] | Fax: [REDACTED] | E-mail: [REDACTED] | Web site:
www.eskaaustralia.com.au

[REDACTED] Tel: [REDACTED] | E-mail: [REDACTED]



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