

Kline, Cliff

From: Free, Donna
Sent: Wednesday, December 01, 2004 11:30 AM
To: 'Dawisha, Sahar'; 'Allen, Samie Niver'
Cc: Michael, Maher; Kline, Cliff
Subject: FW: response to Tables 13.1 and 13.3.1

Hi Sahar

Per your request, we have prepared the response and table (below) with the number of implants. Let us know if you need anything else.

Thanks

Donna

Response:

Below is a table detailing the implants excluded from analysis in Tables 13.1 and 13.3.1, years 1 and 2, because the patients had their MRI scans after explant of their original Core Gel implants. The last column details the 21 implants that were excluded from either Table 13.1 or Table 13.3.1. You are correct, the patient in the second row is 419.003. This has been corrected in the table below.

Implants Excluded from Analysis because they had MRI scan after Original Core Gel Implants Explanted

| Patient | 13.1 | 13.3.1 Year 1 | 13.3.1 Year 2 | Overall Implants |
|--------------|------|---------------|---------------|------------------|
| | 2 | 2 | 2 | 2 |
| | 2 | 2 | 2 | 2 |
| | 1 | 1 | 1 | 1 |
| | 2 | 2 | 2 | 2 |
| | 1 | 1 | 1 | 1 |
| | 1 | 1 | | 1 |
| | | | 1 | 1 |
| | 1 | | 1 | 1 |
| | | | 2 | 2 |
| | 2 | 2 | | 2 |
| | 2 | 2 | 2 | 2 |
| | | | 2 | 2 |
| | | | 2 | 2 |
| Total | 14 | 13 | 18 | 21 |

-----Original Message-----

From: Dawisha, Sahar [mailto:SXD@CDRH.FDA.GOV]
Sent: Wednesday, December 01, 2004 7:28 AM
To: 'Michael, Maher'; Dawisha, Sahar
Cc: Allen, Samie Niver; Kline, Cliff; Free, Donna

3075 1112 1112 1112

Subject: RE: response to Tables 13.1 and 13.3.1

Mack

It would be easier for me if you put the # of implants directly into the table below

**Patients Excluded from Analysis
because they had MRI scan after
Original Core Gel Implants Explanted**

| Patient | 13.1 | 13.3.1 Year 1 | 13.3.1 Year 2 |
|--------------|------|------------------|------------------|
| | X | X | X |
| | X | X | X |
| | X | X | X |
| | X | X | X |
| | X | X | X |
| | X | X | |
| | | | X |
| | X | | X |
| | | | X |
| | X | X | |
| | X | X | X |
| | | | X |
| | | | X |
| Total | 9 | 8 | 11 |

Thanks,
Sahar

-----Original Message-----

From: Michael, Maher [mailto:MMichael@mentorcorp.com]
Sent: Monday, November 29, 2004 2:39 PM
To: 'Dawisha, Sahar'
Cc: Allen, Samie Niver; Kline, Cliff; Free, Donna
Subject: RE: response to Tables 13.1 and 13.3.1

Dear Dr. Dawisha

Please, find attached our response to your questions of November 24th, 2004. If you have any additional questions, please let us know.

Thanks
Mack

-----Original Message-----

From: Dawisha, Sahar [mailto:SXD@CDRH.FDA.GOV]
Sent: Wednesday, November 24, 2004 12:19 PM
To: 'Free, Donna'; Dawisha, Sahar
Cc: Allen, Samie Niver; Michael, Maher; Kline, Cliff
Subject: RE: response to Tables 13.1 and 13.3.1

Thanks Donna.

Could you provide the number of implants associated with the attachment?

Also, could you clarify the number of implants pertaining to each patient # shown in Table 5.4.13.1-C in Attachment 18?

Thanks,
Sahar

-----Original Message-----

From: Free, Donna [mailto:DFree@mentorcorp.com]

Sent: Friday, November 19, 2004 1:14 PM

To: 'Dawisha, Sahar'

Cc: 'Allen, Samie Niver'; Michael, Maher; Kline, Cliff

Subject: response to Tables 13.1 and 13.3.1

Hi Sahar,

Attached please find our response to your questions regarding MRI accounting tables 13.1 and 13.3.1. Please let us know if you require additional information.

Thanks and have a nice weekend.

Donna