

**From:** Palmisano, Brent  
**Sent:** 09/19/2011 10:53:20 AM  
**To:** Sherry, John  
**CC:** Matusovsky, Maya  
**Subject:** RE: LITE PFR Kits Cleared for US

I'm taking the OAB call from home.

Maya, FYI if marketing is needed.  
BP

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**From:** Sherry, John  
**Sent:** Monday, September 19, 2011 10:50 AM  
**To:** Palmisano, Brent  
**Cc:** Smith, Charles; Vialle, George; Intoccia, Al; Raneri, Joe; Daignault, Kenneth  
**Subject:** RE: LITE PFR Kits Cleared for US

Brent there is a meeting at 11am today that will iron out the labeling and launch ready issues which need to be resolved. Resin availability was one item - now resolved - see below.

Please join if you would like.  
MAR ConRm 200-3-Uro/WH R&D 1 (VC)

John

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**From:** Intoccia, Al  
**Sent:** Monday, September 19, 2011 7:04 AM  
**To:** Raneri, Joe; Daignault, Kenneth  
**Cc:** Smith, Charles; Vialle, George; Sherry, John  
**Subject:** RE: LITE PFR Kits Cleared for US

Joe,

Lets plan on using Marlex resin for Pinnacle Lite.

Al

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**From:** Raneri, Joe  
**Sent:** Friday, September 16, 2011 11:49 AM  
**To:** Daignault, Kenneth; Intoccia, Al  
**Cc:** Smith, Charles  
**Subject:** RE: LITE PFR Kits Cleared for US

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I just set up a meeting for next week to determine what needs to happen and establish a schedule

**From:** Daignault, Kenneth  
**Sent:** Friday, September 16, 2011 11:38 AM  
**To:** Raneri, Joe; Intoccia, Al  
**Cc:** Smith, Charles  
**Subject:** RE: LITE PFR Kits Cleared for US

This will be really huge for the division, particularly with all the mesh stuff going on with the FDA. How soon can we make the label changes and launch?

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**From:** Raneri, Joe  
**Sent:** Friday, September 16, 2011 11:30 AM  
**To:** Intoccia, Al  
**Cc:** Smith, Charles; Daignault, Kenneth  
**Subject:** FW: LITE PFR Kits Cleared for US

Al,

I will continue to pursue completion of everything required for US launch of Pinnacle LITE. We will need a decision on this as it will significantly impact the run out date for the Marlex resin. The current plan has no US sales for Pinnacle LITE.

Joe

**From:** Berry, Michelle (Marlborough)  
**Sent:** Friday, September 16, 2011 9:40 AM  
**To:** Raneri, Joe; Petricca, John; Connor, Janice; Foust, Dawn; Cornell (Scalero), Mary Ann; LeCompte, Fran; Goddard, James; Dao, Cang; Woodhull, Lindsey; Matusovsky,

Maya; Horton, Peter; Gauvin, Chris; Shreeve, David; Naze, James; Shah, Vijay;  
Goncalves, John; Graves, Thomas; Celmer, Christine; Kenison, Lynne; Courtois, Janice  
**Subject:** LITE PFR Kits Cleared for US

Good Friday Morning,

It has been a long road but at last I have some welcome news to share with you.  
Today, we received the FDA clearance letter for the LITE Pelvic Floor Repair Kits.

**CONGRATULATIONS** to the entire **TEAM!**

Please note that prior to receiving the clearance letter, FDA has asked us to make an additional wording change to the product DFU. The labeling team has already created red-lines and will create the CR to have these red-lines approved. Joe, can you call a team meeting for next week to help lay out the steps required to launch in the US? At our next meeting I would be glad to share with you a summary of the FDA panel meeting and Maya may have a recap from AUGs.

Thanks everyone for your help and support.

Talk to you soon.