

Phillips Sumika: Marlex HGX-030-01 (Polypropylene) July 14, 2011 Background/Update

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History

- **July 2005**
 - Contract with Phillips Summika expiring Sept 2005
 - During renegotiation to extend, supplier refuses to continue to sell to BSC for use in Medical Device, but allows lifetime buy per terms of contract (up to 40K lbs maximum allowed)
 - BSC purchased 4K lbs; equivalent to 10 years production
- **June 2010**
 - Considered “Bullpen” project in Urology/Women’s Health Sustaining Dashboard PIB
- **October 2010**
 - Charlie Smith’s team identifies Borealis resin as suitable replacement; confirmed by results from Nelson Labs
 - Global Sourcing is contacted to begin contract discussions with Borealis
 - Initial discussions positive
- **November 2010**
 - Borealis communicates they have determined “they will not knowingly sell their product for use in medical device”
 - Project reactivated from “Bullpen” in Urology/Women’s Health Sustaining Dashboard PIB

Jan - June 2011

- **January 2011**
 - Global Sourcing searches market for additional HGX-030-01
 - PolyOne, Foster, Sabic, RTP, Solvay, Teleflex, Ashland, etc.
- **March 2011**
 - Due to the proliferation of new products and increasing sales, inventory forecasted now to only last 2-3 more years
 - Global Sourcing contacts Phillips Summika directly to purchase additional Marlex.
 - Phillips Summika confirms:
 - Entire HGX-030-01 product line was discontinued several years ago due to low demand
 - BSC can request a special run with following criteria:
 - Not to be used for medical device
 - Minimum buy is 1M lbs, the equivalent of 6 rail cars
 - Material value estimated @ \$2M
 - Even if all criteria above is met; no guarantee Phillips Summika management will approve request
 - Decision made to proceed with purchase of Borealis resin through Tier 3 supplier (Luxilon); no direct link to BSC
- **April 2011**
 - Indemnification/Insurance Agreement
 - Stand alone agreement is developed and approved by Legal in anticipation of future discussions with resin suppliers unwilling to sell to BSC for use in medical device
 - Team agrees not to approach current suppliers; use if future negotiations through normal channels unsuccessful
- **Supply Chain**
 - > MedVenture (Assemblies / Kits) Tier 1
 - > Proxy (Mesh) Tier 2
 - > Luxilon (Fibers) Tier 3
 - > Phillips (Resin) Tier 4

Prepared by: A Charest, July 14, 2011

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EXHIBIT

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- **July 2011**

- Material selection changed to LyondellBasell Profax material
- PO placed to have Proxy test Profax material
- Current inventory of Marlex expected to run out June 2012
- New Mesh Regulations from FDA introduced

- **July 19 – Option 1**

Supplier Management Outpost in Shanghai Michael (Zhao Ying)

- Still in evaluation, but we have received a positive read on HGX-030-01 being available in China (Distributor) – Guangdong (Hong Kong)
- Don't get your hope up yet, still too early
- One distributor is out, but mentioned that they can get that material within 2 months
- Another distributor needs to do more ground work, but believes that they have it on stock.
- Other distributors have the product listed on their web page.
- **Open questions.**
 - Are we going to place the order, or will Luxilon place the order.
 - Do we have to add this distributor to our AVL

- **Open questions continued**

- Can someone write a deviation to avoid assessment/re-qual/FAI
- Does the product have a shelf life
- Does the product have storage/handling conditions
- What questions should we ask that we can confirm that it is the right product and that it was stored/handled properly
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- **July 19 – Option 2**

RTi has located 1300 lbs domestically

- 700 lbs virgin resin
- 600 lbs with minimal black flecks

- **ACTIONS:**

- Initiate PO for 700 lbs of virgin resin – Charlie
- Discuss w/Engineering possibility of using 600 lbs w/flecks – Charlie
- Global Sourcing will continue to pursue other sources of material, including leads in China.

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