

**Dragon, Karen E. (CDC/NIOSH/EID)**

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**From:** Powelko, Ron (CDC/NIOSH/NPPTL)  
**Sent:** Wednesday, August 08, 2007 7:41 AM  
**To:** Dragon, Karen E. (CDC/NIOSH/EID)  
**Cc:** Powelko, Ron (CDC/NIOSH/NPPTL); Perrotte, John (CDC/NIOSH/NPPTL)  
**Subject:** FW: Respirator Audit Logic Database  
**Attachments:** NIOSH MAXAIR submittals.xls

Karen for your information.

Ron Powelko, MS, Safety Management  
Quality Assurance Specialist  
Certified Lead Auditor  
National Personal Protective Technology Laboratory  
Respirator Branch  
NIOSH  
412-386-4021

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**From:** Harvey, Karen (CDC/NIOSH/NPPTL)  
**Sent:** Wednesday, August 08, 2007 7:19 AM  
**To:** Powelko, Ron (CDC/NIOSH/NPPTL); Perrotte, John (CDC/NIOSH/NPPTL)  
**Subject:** FW: Respirator Audit Logic Database

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**From:** Allan Schultz [mailto:aschultz@bmdi.com]  
**Sent:** Tuesday, August 07, 2007 7:03 PM  
**To:** Harvey, Karen (CDC/NIOSH/NPPTL)  
**Subject:** Respirator Audit Logic Database

Dear Mr. Harvey:

This e-mail is in response to your "Letter To All Respirator Manufacturers" dated July 11, 2007.

The attached Excel spreadsheet contains a listing of all Bio-Medical Devices NIOSH submittals for the MAXAIR® product line.

The primary manufacturing site for MAXAIR Systems is:

Syntech International  
17171 Daimler Avenue  
Irvine, CA 92614

The applicable ISO standard is ISO 13485.

The product status is indicated for each submittal on the spreadsheet attached.

If additional information is required, and if I can be of further assistance, please contact me.

Regards,

8/8/2007

Allan Schultz  
Bio-Medical Devices  
17171 Daimler Avenue  
Irvine, CA 92614

800-443-3842 x149  
949-936-2056 office direct  
949-295-2513 cell  
[aschultz@bmdi.com](mailto:aschultz@bmdi.com)

Description and Product Part Number	Submittal Date	TN - Number	Approved	Active	Inactive	Obsolete
Helmet 2000-10, battery, belt, filter, etc.	12/14/2000	TN-11832	Approved 4/11/2001	X		
Quality Manual	5/4/2001	TN-11965	Approved 5/24/2001	X		
Site audit response	8/15/2001	TN-12106	Approved 10/4/2001	X		
01031001 - hood all meltblown	8/16/2001	TN12107	Approved 10/16/2001	X		
Submittal for Quality Manual	10/1/2001	TN-12167	Approved 11/02/2001	X		
Submittal for p/n 01031001, 01031041	4/11/2002	TN-12423	Approved 7/25/2002	X		
Submittal for p/n 2000-25	4/11/2002	TN-12425	Approved 7/5/2002	X		
Submittal p/n 2000-01	7/15/2002	TN-12529	Approved 12/27/2002	X		
Submittal p/n 2000-25	7/15/2002	TN-12537	Approved 1/31/2003	X		
Submittal for Quality Manual	10/3/2002	TN-12659	Approved 02/05/2003	X		
re-usable pre-filter	12/2/2002	TN-12706	Approved 4/17/2003	X		
Submittal for p/n 2000-06, 2000-08, 2000-12ML & SM, 2000-25, 2000-35	12/2/2002	TN-12711	Approved 5/30/2003	X		
Submittal for p/n 2000-03, 2000-30, 2000-50	6/5/2003	TN-12953	Approved 8/12/2003	X		
Submittal for p/n 2000-01	6/5/2003	TN-12951	Approved 7/10/2003	X		
Submittal p/n 2000-07	7/7/2003	TN-13005	Approved 10/15/2003	X	X	
Submittal for p/n 2000-03SH, 2000-23	8/26/2003	TN-13076	Approved 12/23/03	X	X	
Submittal for p/n 2000-03SH REV B	7/27/2003	TN-13077	Approved 1/29/04	X	X	
Submittal for p/n 2000-03SH REV. C	7/27/2003	TN-13078	Approved 2/11/2004	X	X	
Submittal for p/n 2000-25D - pre-filter	10/2/2003	TN-13150	Approved 1/13/2004	X		
Submittal for p/n 02531132 Chin strap attachment to maxair	5/7/2004	TN-13478	Approved 7/28/04	X		
Submittal for 2000-36 4.4 LITHIUM BATTERY	10/24/2003	TN-13172	Approved 2/13/2004	X		
Submittal for Maxair -Hood 2000-25DM	5/4/2004	TN-13479	Approved 7/28/2004	X		
Submittal for Maxair battery switch p/n 2000-30sw	5/10/2004	TN-13485	Approved 8/2/2004	X	X	
Resubmittal Maxair White Hood Media	10/12/2004	TN-13868	Approved 03/10/2005	X		
Submittal for Lithium ion Battery Charger p/n 01431078 (2000-52)	11/23/2004	TN-13869	Approved 03/23/2005	X		
Submittal for Split and Packaging procedure	12/14/2004	TN14024	Approved 07/19/2005	X		
Submittal for Maxair- Lumar Belt Clip p/n 00731047	1/24/2004	TN-14005	Approved 07/18/2005	X		
Submittal for added battery p/n 01532032 to the Maxair Helmet	06/01/2005	TN-14068	Approved 08/18/2005	X		
Submittal for split assembly and packaging procedure for 2000-03imp	7/11/2005	TN-14179	Approved 10/06/2005	X		
Submittal for Syntech Quality Manual	2/23/2006	TN-14404	Approved 04/26/06	X		
Submittal for Lithium ion battery 2000-30 with switch p/n 2000-30	11/2/2005	TN-14501	Approved 7/15/2006	X		
Syntech De Baja Quality Manual	7/21/2006	TN-14661	Approved 07/28/2006	X		
Cosmetic defect found on 00731145 helmet (Resubmittal)	11/1/2006	TN-14834	Approved 12/06/06	X		