



Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
(800) 451-6027
www.IN.gov/idem

TO: Interested Parties / Applicant
DATE: August 9, 2005
RE: Smiths Medical ASD, Inc. / 089-19157-00164
FROM: Paul Dubenetzky
Chief, Permits Branch
Office of Air Quality

Notice of Decision: Approval - Registration

Please be advised that on behalf of the Commissioner of the Department of Environmental Management, I have issued a decision regarding the enclosed matter. Pursuant to IC 4-21.5-3-4(d) this order is effective when it is served. When served by U.S. mail, the order is effective three (3) calendar days from the mailing of this notice pursuant to IC 4-21.5-3-2(e).

If you wish to challenge this decision, IC 4-21.5-3-7 requires that you file a petition for administrative review. This petition may include a request for stay of effectiveness and must be submitted to the Office of Environmental Adjudication, 100 North Senate Avenue, Government Center North, Room 1049, Indianapolis, IN 46204, **within eighteen (18) calendar days of the mailing of this notice**. The filing of a petition for administrative review is complete on the earliest of the following dates that apply to the filing:

- (1) the date the document is delivered to the Office of Environmental Adjudication (OEA);
- (2) the date of the postmark on the envelope containing the document, if the document is mailed to OEA by U.S. mail; or
- (3) The date on which the document is deposited with a private carrier, as shown by receipt issued by the carrier, if the document is sent to the OEA by private carrier.

The petition must include facts demonstrating that you are either the applicant, a person aggrieved or adversely affected by the decision or otherwise entitled to review by law. Please identify the permit, decision, or other order for which you seek review by permit number, name of the applicant, location, date of this notice and all of the following:

- (1) the name and address of the person making the request;
- (2) the interest of the person making the request;
- (3) identification of any persons represented by the person making the request;
- (4) the reasons, with particularity, for the request;
- (5) the issues, with particularity, proposed for considerations at any hearing; and
- (6) identification of the terms and conditions which, in the judgment of the person making the request, would be appropriate in the case in question to satisfy the requirements of the law governing documents of the type issued by the Commissioner.

If you have technical questions regarding the enclosed documents, please contact the Office of Air Quality, Permits Branch at (317) 233-0178. Callers from within Indiana may call toll-free at 1-800-451-6027, ext. 3-0178.

Enclosures
FN-REGIS.dot 1/10/05



INDIANA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

We make Indiana a cleaner, healthier place to live.

Mitchell E. Daniels, Jr.
Governor

Thomas W. Easterly
Commissioner

100 North Senate Avenue
Indianapolis, Indiana 46204
(317) 232-8603
(800) 451-6027
www.IN.gov/idem

Mark Stuart
Smiths Medical ASD, Inc.
5700 West 23rd Avenue
Gary, IN 46406

August 9, 2005

Re: Registered Construction and Operation Status,
089-19157-00164

Dear Mr. Stuart:

The application from Smiths Medical ASD, Inc., received on May 24, 2004, has been reviewed. Based on the data submitted and the provisions in 326 IAC 2-5.1, it has been determined that the following, to be located at 5700 West 23rd Avenue, in Gary, Indiana, is classified as registered:

One (1) surgical appliance and supplies manufacturing operation, including:

- (a) one (1) wire cell production process,
- (b) one (1) molding and extrusion process, and
- (c) one (1) assembly and packaging process.

This registration is the first registration issued to this source. The source may operate according to 326 IAC 2-5.5.

An authorized individual shall provide an annual notice to the Office of Air Quality and Gary Department of Environmental Affairs that the source is in operation and in compliance with this registration pursuant to 326 IAC 2-5.1-2(f)(3). The annual notice shall be submitted to:

**Compliance Data Section
Office of Air Quality
100 North Senate Avenue
Indianapolis, IN 46204**

and

**Gary Department of Environmental Affairs
504 North Broadway, Suite 1012
Gary, IN 46402**

no later than March 1 of each year, with the annual notice being submitted in the format attached.

An application or notification shall be submitted in accordance with 326 IAC 2 to the Office of Air Quality (OAQ) and Gary Department of Environmental Affairs if the source proposes to construct new emission units, modify existing emission units, or otherwise modify the source.

Sincerely,

Original signed by
Nisha Sizemore, Section Chief
Permits Branch
Office of Air Quality

SDF

cc: File - Lake County
Lake County Health Department
Air Compliance – Rick Massoels/Ramesh Tejuja
Northwest Regional Office
Permit Tracking
Compliance Data Section
Gary Department of Environmental Affairs

Registration Annual Notification

This form should be used to comply with the notification requirements under 326 IAC 2-5.1-2(f)(3).

Company Name:	Smiths Medical ASD, Inc.
Address:	5700 West 23 rd Avenue
City:	Gary, IN 46406
Authorized individual:	Mark Stuart
Phone #:	219-989-9150
Registration #:	089-19157-00164

I hereby certify that the surgical appliance and supplies manufacturing operation is still in operation and is in compliance with the requirements of Registration 089-19157-00164.

Name (typed):
Title:
Signature:
Date:

**Indiana Department of Environmental Management
Office of Air Quality**

Technical Support Document (TSD) for a Source Registration

Source Background and Description:

Source Name: Smiths Medical ASD, Inc.
 Source Location: 5700 West 23rd Avenue, Gary, Indiana 46406
 County: Lake
 SIC Code: 3842
 Registration No.: 089-19157-00164
 Permit Reviewer: SDF

The Office of Air Quality (OAQ) has reviewed an application from Smiths Medical ASD, Inc., requesting a registration for one (1) surgical appliance and supplies manufacturing operation, including:

- (a) one (1) wire cell production process,
- (b) one (1) molding and extrusion process, and
- (c) one (1) assembly and packaging process.

The pollutants generated by the surgical appliance and supplies manufacturing operation are volatile organic compounds (VOC) and hazardous air pollutants (HAP).

The source VOC, single HAP, and combined HAP potential to emit before controls are estimated to be 18.63, 2.28, and 3.35 tons/yr, respectively.

Therefore, the source shall be issued a registration pursuant to 326 IAC 2-5.1-2(a)(1)(C) which states that all new sources with a VOC potential to emit before controls greater than 10 tons per year, but less than 25 tons per year, shall be permitted via a registration.

Stack Summary

Stack/Vent ID	Stack Type	Stack Height	Stack Diameter	Flowrate (acfm)	Temperature (°F)
1	General Exhaust Fan	10'	10"	1000	Ambient
2	General Exhaust Fan	10'	10"	1000	Ambient
3	General Exhaust Fan	10'	10"	1000	Ambient
4	General Exhaust Fan	10'	10"	1000	Ambient
5	General Exhaust Fan	10'	10"	1000	Ambient
6	General Exhaust Fan	10'	10"	1000	Ambient
7	General Exhaust Fan	10'	10"	1000	Ambient
8	Damper Vent	10'	12"	1000	Ambient
9	General Exhaust Fan	10'	10"	1000	Ambient
10	General Exhaust Fan	22'	10"	1000	400°F
11	General Exhaust Fan	22'	10"	1000	400°F

Insignificant Activities

There are no insignificant activities associated with the source.

Existing Approvals

The source has been operating under construction permit 089-5743-00164, issued on September 27, 1996.

Recommendation

The staff recommends to the Commissioner that the Registration be approved. This recommendation is based on the following facts and conditions.

Unless otherwise stated, information used in this review was derived from the application and additional information submitted by the applicant on September 21, 2004 and August 2, 2005.

Emission Calculations

The emissions generated by the proposed source are VOC and HAP emissions from the wire cell production, molding and extrusion, and assembly and packaging processes.

(a) Potential to Emit Before Controls:

The VOC and HAP potential to emit before controls are determined based on the material maximum usage in pounds per hour, weight fraction of the pollutant, emissions before controls, and 8760 hours of operation.

$$\text{lb/hr} * \text{wt fraction poll.} * 8760 \text{ hr/yr} * 1/2000 \text{ ton/lb} = \text{tons poll./yr}$$

Process	Material	lb/hr	wt frac. VOC	wt frac. Hexane	Wt. frac. Xylene	wt frac. MIBK
Wire Cell Prod.	heptane/hexane	2.08	1.00	0.25	-	-
Mold/Extrusion	3-6060 primer	0.004	0.95	-	-	-
	varox lupersol	0.004	0.04	-	-	0.95
	mold release	0.03	1.00	-	-	-
Clean/Package	IPA	1.90	1.00	-	-	-
Print/Silk Screen	sol-gen-003-1	0.24	1.00	-	1.00	-

Process	Material	VOC (tons/yr)	Hexane (tons/yr)	Xylene (tons/yr)	MIBK (tons/yr)
Wire Cell Prod.	heptane/hexane	9.11	2.28	-	-
Mold/Extrusion	3-6060 primer	0.02	-	-	-
	varox lupersol	0.001	-	-	0.02
	mold release	0.13	-	-	-
Clean/Package	IPA	8.32	-	-	-
Print/Silk Screen	sol-gen-003-1	1.05	-	1.05	-
Total		18.63	2.28	1.05	0.02

The total combined HAP potential to emit before controls is the sum of the estimated hexane, xylene, and MIBK emissions.

$$2.28 \text{ tons Hexane/yr} + 1.05 \text{ tons Xylene/yr} + 0.02 \text{ ton MIBK/yr} = \mathbf{3.35 \text{ tons HAP/yr}}$$

(b) Potential to Emit After Controls:

The source emissions are uncontrolled. Therefore, the potential to emit after controls are equal to the estimated

potential to emit before controls.

	VOC (tons/yr)	Worst Case Single HAP (tons/yr)	Combined HAP (tons/yr)
Source	18.63	2.28	3.35

Potential To Emit

Pursuant to 326 IAC 2-1.1-1(16), Potential to Emit is defined as “the maximum capacity of a stationary source to emit any air pollutant under its physical and operational design. Any physical or operational limitation on the capacity of a source to emit an air pollutant, including air pollution control equipment and restrictions on hours of operation or type or amount of material combusted, stored, or processed shall be treated as part of its design if the limitation is enforceable by the U. S. EPA.”

This table reflects the PTE before controls due to the proposed changes. Control equipment is not considered federally enforceable until it has been required in a federally enforceable permit.

Pollutant	Potential To Emit (tons/year)
PM	-
PM-10	-
SO ₂	-
VOC	18.63
CO	-
NO _x	-

Note: For the purpose of determining Title V applicability for particulates, PM-10, not PM, is the regulated pollutant in consideration.

HAP's	Potential To Emit (tons/year)
Worst case Single HAP	2.28
Combined HAP	3.35

Since the source VOC potential to emit before controls is greater than 10 tons per year but less than 25 tons per year, the source shall be issued a registration pursuant to 326 IAC 2-5.1-2(a)(1)(C) which states that all new sources with VOC emissions that are uncontrolled and have an estimated VOC potential to emit greater than 10 tons per year, but less than 25 tons per year, shall be permitted via a registration.

County Attainment Status

The source is located in Lake County.

Pollutant	Status
PM10	attainment
PM2.5	nonattainment
SO ₂	attainment
NO _x	attainment
1-hour Ozone	attainment
8-hour Ozone	nonattainment
CO	attainment

Lead	attainment
------	------------

- (a) Volatile organic compounds (VOC) and Nitrogen Oxides (NOx) are regulated under the Clean Air Act (CAA) for the purposes of attaining and maintaining the National Ambient Air Quality Standards (NAAQS) for ozone. Therefore, VOC emissions and NOx are considered when evaluating the rule applicability relating to the ozone standards. Lake County has been designated as nonattainment for 8-hour ozone. Therefore, VOC emissions and NOx were reviewed pursuant to the requirements for Emission Offset, 326 IAC 2-3.
- (b) Lake County has been classified as nonattainment for PM2.5. U.S. EPA has not yet established the requirements for Emission Offset, 326 IAC 2-3 for PM 2.5 emissions. Therefore, until the U.S. EPA adopts specific provisions for PSD review for PM2.5 emissions, it has directed states to regulate PM10 emissions as surrogate for PM2.5 emissions.
- (c) Lake County has been classified as attainment or unclassifiable for all of the other criteria pollutants. Therefore, these emissions were reviewed pursuant to the requirements for Prevention of Significant Deterioration (PSD), 326 IAC 2-2.

New Source Emissions

New source federal major source definition (emissions after controls, based upon 8760 hours of operation per year at rated capacity and/or as otherwise limited):

	PM (tons/yr)	PM10 (tons/yr)	SO2 (tons/yr)	NOX (tons/yr)	VOC (tons/yr)	CO (tons/yr)	Single HAP (tons/yr)	Comb. HAP (tons/yr)
New Source	-	-	-	-	18.63	-	2.28	3.65

Federal Rule Applicability

40 CFR 60, Subpart QQ, Standards of Performance for the Graphic Arts Industry: Publication Rotogravure Printing:

The requirements of 40 CFR 60, Subpart QQ do not apply to the silk screening units associated with the assembly process because the silk screening units are not publication rotogravure printing presses.

State Rule Applicability - Individual Facilities

- (a) 326 IAC 8-2-5 (Paper Coating Operations):

The requirements of 326 IAC 8-2-5 do not apply to the silk screening units associated with the assembly process because the silk screening units are not web coaters or saturation processes.

- (b) 326 IAC 8-5-5 (Graphic Arts Operations):

The requirements of 326 IAC 8-5-5 do not apply to the silk screening units associated with the assembly process because the silk screening units are not packaging rotogravure, publication rotogravure, or flexographic printing processes.

- (c) 326 IAC 8-6 (Organic Solvent Emission Limitations):

The requirements of 326 IAC 8-6 do not apply to the proposed source because the source VOC potential to emit before controls is less than the applicable level of 100 tons per year.

- (d) 326 IAC 8-7 (Specific VOC Reduction Requirements for Lake County):

The requirements of 326 IAC 8-7-2 do not apply to the proposed source because the source VOC potential to emit before controls is less than the applicable source level of 25 tons per year and there are no "coating facilities" which emit or have the potential to emit greater than or equal 25 tons per year.

(e) 326 IAC 8-1-6 (New Facilities; General Reduction Requirements):

Although there are no other Article 8 rules that apply, the source is not subject to the requirements of 326 IAC 8-1-6 because the source VOC potential to emit before controls is less than the applicable level of 25 tons per year.

Conclusion

The proposed surgical appliance and supplies manufacturing operation shall be operated according to requirements of Registration 089-19157-00164.