

**ALABAMA DEPARTMENT OF
ENVIRONMENTAL MANAGEMENT**

IN THE MATTER OF:

**Orchid Orthopedic Solutions Alabama, LLC
Arab, Marshall County, Alabama
EPA Identification Number ALD063671093**

Consent Order No. 19-XXX-CHW

PREAMBLE

This Special Order by Consent is made and entered into by the Alabama Department of Environmental Management (hereinafter “the Department” or “ADEM”) and Orchid Orthopedic Solutions Alabama, LLC (hereinafter “Orchid Orthopedics”) pursuant to the provisions of the Alabama Environmental Management Act, Ala. Code §§ 22-22A-1 to 22-22A-16, as amended, and the Alabama Hazardous Wastes Management and Minimization Act (hereinafter “AHWMMA”), Ala. Code §§ 22-30-1 to 22-30-24, as amended, and the regulations promulgated pursuant thereto.

STIPULATIONS

1. Orchid Orthopedic Solutions Alabama, LLC (hereinafter “Orchid Orthopedics”), a domestic limited liability company, is a manufacturer of orthopedic instruments and medical implant devices with EPA Identification Number ALD063671093, located at 331 City Park Drive South East in Arab, Marshall County, Alabama. Orchid Orthopedics, as a result of its operations at the facility, was a large quantity generator of hazardous waste and a small quantity handler of universal waste, as those terms are defined in ADEM Admin. Code Div. 14, at all times relevant to this action.

2. The Department is a duly constituted department of the State of Alabama pursuant to Ala. Code §§ 22-22A-1 to 22-22A-16, as amended.

3. Pursuant to Ala. Code § 22-22A-4(n), the Department is the state agency responsible for the promulgation and enforcement of solid and hazardous waste regulations in accordance with the federal Solid Waste Disposal Act §§ 1002 to 11012, 42 U.S.C. §§ 6901 to

6992k, as amended. In addition, the Department is authorized to administer and enforce the provisions of the AHWMMMA, Ala. Code §§ 22-30-1 to 22-30-24, as amended.

DEPARTMENT'S CONTENTIONS

4. On April 15, 2019, a representative of the U. S. Environmental Protection Agency – Region 4 and representatives of the Department's Industrial Hazardous Waste Branch conducted a compliance evaluation inspection (hereinafter "CEI") of Orchid Orthopedics. The CEI and a review of Orchid Orthopedics' compliance showed the following:

(a) ADEM Admin. Code r. 335-14-8-.01(1)(c) requires a permit for the "treatment", "storage", and "disposal" of any "hazardous waste" as identified or listed in Chapter 335-14-2. ADEM Admin. Code r. 335-14-3-.01(7)(a)(2) establishes conditions that a large quantity generator must meet in order to store hazardous waste in tanks without a permit.

Orchid Orthopedics stored chromium waste (D007) in the secondary containment system for the electroplating operation without first obtaining a permit. Orchid Orthopedics captured spills of plating solution and rinsate from its plating system inside a secondary containment system located below the plating line and failed to conduct timely removal of these wastes, thereby operating the secondary containment system as a hazardous waste storage tank. Orchid Orthopedics failed to meet the conditional exclusions applicable to storage of hazardous waste in a tank by a large quantity generator.

(b) Pursuant to ADEM Admin. Code r. 335-14-3-.01(5)(a)5., satellite accumulation containers must be labeled with the words "Hazardous Waste" and an indication of the hazards of their contents.

Orchid Orthopedics failed to properly label a 5-gallon satellite accumulation container of hazardous waste located at the painting booth.

(c) Pursuant to ADEM Admin. Code r. 335-14-3-.01(7)(a)1.(vi)b., a large quantity generator must conspicuously place "No Smoking" signs wherever there is a hazard from ignitable or reactive waste.

Orchid Orthopedics failed to place “No Smoking” signs at the entrance to the 90-day central accumulation area.

(d) Pursuant to ADEM Admin. Code rs. 335-14-3.01(7)(a)1.(viii) and 335-14-6-.09(6)(b), a large quantity generator’s container storage area must be designed and operated with a base which is free of cracks or gaps and is sufficiently impervious to contain leaks, spills, and accumulated precipitation until the collected material is detected and removed.

Orchid Orthopedics failed to provide an adequate containment system in all areas where hazardous waste was stored. The coating on the floor of the containment system in the 90-day central accumulation area was not free of cracks and gaps as required.

(e) Pursuant to ADEM Admin. Code r. 335-14-3-.01(7)(a)7.(iv), the generator must maintain the following records at the facility: the job title for each position at the facility related to hazardous waste management, and the name of the employee filling each job; a written job description for each position; a written description of the type and amount of both introductory and continuing training that will be given to each person filling a position.

Orchid Orthopedics failed to provide for review the job titles and a written job description for all employees that handled hazardous waste in the electroplating area.

(f) Pursuant ADEM Admin. Code r. 335-14-11-.02(4)(d)2., a small quantity handler of universal waste must immediately clean up and place in a container any lamp that is broken and must place in a container any lamp that shows evidence of breakage, leakage, or damage that could cause the release of mercury or other hazardous constituents to the environment.

Orchid Orthopedics failed to clean up one broken fluorescent lamp located in the loft above the maintenance area.

(g) Pursuant to ADEM Admin. Code r. 335-14-11-.02(5)(e), a small quantity handler of universal waste must label or mark each waste lamp or container of waste lamps clearly with one of the following phrases: “Universal Waste-Lamp(s),” or “Waste Lamp(s),” or “Used Lamps.”

Orchid Orthopedics failed to label all containers of spent fluorescent lamps.

(h) Pursuant to ADEM Admin. Code r. 335-14-11-.02(6)(c), a small quantity handler of universal waste who accumulates universal waste must to be able to demonstrate the length of

time that the universal waste has accumulated from the date that it became a waste or was received.

Orchid Orthopedics failed to mark containers of spent florescent lamps with an accumulation start date.

(i) Pursuant to ADEM Admin. Code r. 335-14-17-.03(4)(c)1., containers and aboveground tanks used to store used oil at generator facilities must be labeled or marked clearly with the words "Used Oil."

Orchid Orthopedics failed to label three totes containing used oil with the words "Used Oil".

5. On June 4, 2019, the Department issued a Notice of Violation to Orchid Orthopedics which cited violations of the hazardous waste regulations that were discovered during the CEI.

6. On July 11, 2019, the Department received Orchid Orthopedics' response to the June 4, 2019 Notice of Violation.

7. Pursuant to Ala. Code § 22-22A-5(18), as amended, in determining the amount of any penalty, the Department must give consideration to the seriousness of the violation(s), including any irreparable harm to the environment and any threat to the health or safety of the public; the standard of care manifested by such person; the economic benefit which delayed compliance may confer upon such person; the nature, extent, and degree of success of such person's efforts to minimize or mitigate the effects of such violation(s) upon the environment; such person's history of previous violations; and the ability of such person to pay such penalty. Any civil penalty assessed pursuant to this authority shall not exceed \$25,000.00 for each violation, provided however, that the total penalty assessed in an order issued by the department shall not exceed \$250,000.00. Each day such a violation continues shall constitute a separate violation. In arriving at this civil penalty, the Department has considered the following:

(a) **SERIOUSNESS OF THE VIOLATIONS:** In arriving at the civil penalty, the Department considered the general nature and magnitude of the violations along with the

available evidence of irreparable harm to the environment and threat to the health or safety of the public.

(b) **THE STANDARD OF CARE:** In considering the standard of care manifested by Orchid Orthopedics, the Department noted that the violations described above were non-technical and easily avoidable. Consequently, Orchid Orthopedics has failed to exhibit a standard of care commensurate with the applicable regulatory standards.

(c) **ECONOMIC BENEFIT WHICH DELAYED COMPLIANCE MAY HAVE CONFERRED:** The Department has determined that there was no significant economic benefit gained by Orchid Orthopedics as a result of the violations referenced herein.

(d) **EFFORTS TO MINIMIZE OR MITIGATE THE EFFECTS OF THE VIOLATION UPON THE ENVIRONMENT:** There are no known environmental effects to mitigate as a result of the violations referenced herein.

(e) **HISTORY OF PREVIOUS VIOLATIONS:** Based on a review of Department records, Orchid Orthopedics has no history of previous violations.

(f) **THE ABILITY TO PAY:** Orchid Orthopedics has not alleged an inability to pay the civil penalty.

(g) **OTHER FACTORS:** It should be noted that this Special Order by Consent is a negotiated settlement and, therefore, the Department has compromised the amount of the penalty that is warranted in the spirit of cooperation and the desire to resolve this matter amicably without incurring the unwarranted expense of litigation (see Attachment A, which is made a part of the Department's Contentions).

8. The Department neither admits nor denies Orchid Orthopedics' contentions, which are set forth below. The Department has agreed to the terms of this Special Order by Consent in an effort to resolve the alleged violations cited herein without the unwarranted expenditure of State resources in further prosecuting the alleged violations. The Department has determined that the terms contemplated in this Special Order by Consent are in the best interest of the citizens of Alabama.

FACILITY'S CONTENTIONS

9. Orchid Orthopedics neither admits nor denies the Department's contentions. Orchid Orthopedics consents to abide by the terms of this Special Order by Consent and to pay the civil penalty assessed herein.

ORDER

Therefore, without admitting that it has violated any statutes or regulations, Orchid Orthopedics, along with the Department, desires to resolve and settle the alleged violations cited above. The Department has carefully considered the facts available to it and has considered the six penalty factors enumerated in Ala. Code § 22-22A-5(18)c. , as amended, as well as the need for timely and effective enforcement and the Department believes that the following conditions are appropriate to address the violations alleged herein. Therefore, the Department and Orchid Orthopedics agree to enter into this Special Order by Consent with the following terms and conditions:

A. Orchid Orthopedics agrees to pay to the Department a civil penalty in the amount of \$16,500 in settlement of the violations alleged herein within forty-five days of the effective date of this Special Order by Consent. Failure to pay the civil penalty within forty-five days from the effective date may result in the Department's filing a civil action in the Circuit Court of Montgomery County to recover the civil penalty.

B. Orchid Orthopedics agrees that all penalties due pursuant to this Special Order by Consent shall be made payable to the Alabama Department of Environmental Management by certified or cashier's check or other payment methods acceptable to the Department and shall be remitted to:

Office of General Counsel
Alabama Department of Environmental Management
P.O. Box 301463
Montgomery, Alabama 36130-1463

Any payment submitted to the Department pursuant to this Special Order by Consent shall reference Orchid Orthopedics' name and address, and the ADEM Administrative Order number of this action.

C. That, within 30 days of issuance of this Order, Orchid Orthopedics shall submit documentation demonstrating the integrity of the secondary containment system associated with the electroplating operation. The information should include, at a minimum, any evidence of a failure of this system that is observed following removal of the wastes observed in storage during the compliance evaluation inspection, as well as any corrective actions implemented with this system.

D. Orchid Orthopedics agrees that, independent of this Special Order by Consent, Orchid Orthopedics shall comply with all terms, conditions, and limitations of the AHWMMMA, Ala. Code §§ 22-30-1 to 22-30-24, as amended, and the regulations promulgated pursuant thereto.

E. The Department and Orchid Orthopedics (hereinafter the "parties") agree that this Special Order by Consent shall apply to and be binding upon both parties, their directors, officers, and all persons or entities acting under or for them. Each signatory to this Special Order by Consent certifies that he or she is fully authorized by the party he or she represents to enter into the terms and conditions of this Special Order by Consent, to execute the Special Order by Consent on behalf of the party represented, and to legally bind such party.

F. The parties agree that, subject to the terms of these provisions and subject to provisions otherwise provided by statute, this Special Order by Consent is intended to operate as a full resolution of the alleged violations cited herein.

G. Orchid Orthopedics agrees that it is not relieved from any liability if it fails to comply with any provision of this Special Order by Consent.

H. For purposes of this Special Order by Consent only, Orchid Orthopedics agrees that the Department may properly bring an action to compel compliance with the terms and conditions contained herein in the Circuit Court of Montgomery County.

I. The parties agree that the sole purpose of this Special Order by Consent is to resolve and dispose of all allegations and contentions stated herein concerning the factual circumstances referenced herein. Should additional facts and circumstances be discovered in the future which would constitute possible violations not addressed in this Special Order by Consent, then such future violations may be addressed in orders as may be issued by the Director, litigation initiated by the Department, or such other enforcement action as may be appropriate; Orchid Orthopedics agrees not to object to such future orders, litigation, or enforcement action based on the issuance of this Special Order by Consent if future orders, litigation, or other enforcement action address new matters not raised in this Special Order by Consent.

J. The parties agree that this Special Order by Consent shall be considered final and effective immediately upon signature of all parties. This Special Order by Consent shall not be appealable, and Orchid Orthopedics does hereby waive any hearing on the terms and conditions of this Special Order by Consent.

K. The parties agree that this Special Order by Consent shall not affect Orchid Orthopedics' obligation to comply with any federal, State, or local laws or regulations.

L. The parties agree that final approval and entry into this Special Order by Consent are subject to the requirements that the Department give notice of proposed orders to the public, and that the public have at least thirty days within which to comment on the order.

M. The parties agree that, should any provision of this Special Order by Consent be declared by a court of competent jurisdiction or the Environmental Management Commission to be inconsistent with Federal or State law and therefore unenforceable, the remaining provisions hereof shall remain in full force and effect.

N. The parties agree that any modifications of this Special Order by Consent must be agreed to in writing signed by both parties.

O. The parties agree that, except as otherwise set forth herein, this Special Order by Consent is not and shall not be interpreted to be a permit or modification of an existing permit

under Federal, State, or local law, and shall not be construed to waive or relieve Orchid Orthopedics of its obligations to comply in the future with any permit.

Executed in duplicate, with each part being an original.

FACILITY

ALABAMA DEPARTMENT OF ENVIRONMENTAL MANAGEMENT

Brad Hawkins
(Signature of Authorized Representative)

Lance R. LeFleur
Director

Brad Hawkins
(Printed Name)

EHS Specialist
(Printed Title)

8/21/2019
(Date Signed)

(Date Executed)

Attachment A

Orchid Orthopedics Solutions Alabama, LLC
Arab, Marshall County
Facility ID No. ALD063671093

Violation	Number of Violations*	Seriousness of Violation*	Standard of Care*	History of Previous Violation*	
Unpermitted storage of hazardous waste	1	\$10,000	\$7,500	\$0	
Failure to mark satellite accumulation containers with the words "Hazardous Waste"	1	\$100	\$100	\$0	
Failure to post "No Smoking" signs at the central accumulation area	1	\$100	\$100	\$0	
Failure to provide adequate secondary containment for hazardous waste storage areas	1	\$1,000	\$500	\$0	
Failure to maintain documentation of job titles and written job descriptions	1	\$100	\$100	\$0	
Failure to clean up broken universal waste lamps	1	\$250	\$100	\$0	
Failure to mark containers holding universal waste lamps with one of the required phrases	1	\$100	\$100	\$0	
Failure to demonstrate the length of time universal waste lamps had been accumulated on site.	1	\$100	\$100	\$0	
Failure to mark all containers holding used oil with the words "Used Oil"	1	\$100	\$100	\$0	Total of Three Factors
TOTAL PER FACTOR		\$11,850	\$8,700	\$0	\$20,550

Adjustments to Amount of Initial Penalty

Mitigating Factors (-)	\$0	Economic Benefit (+)	\$0
Ability to Pay (-)	\$0	Amount of Initial Penalty	\$20,550
Other Factors (+/-)	(\$4,050)	Total Adjustments (+/-)	(\$4,050)
Total Adjustments (+/-) Enter at Right	(\$4,050)	FINAL PENALTY	\$16,500

Footnotes

* See the "DEPARTMENT'S CONTENTIONS" portion of the Order for a detailed description of each violation and the penalty factors.