

September 3, 2024

Howmedica Osteonics Corporation
dba Stryker Spine
2 Pearl Ct
Allendale NJ 07401

RE: Case No. 24-255

To whom it may concern:

Enclosed you will find a Summary Order issued by the Kansas Board of Pharmacy (Board) in the above-referenced matter. Please read the order in its entirety. In addition, a civil fine has been assessed totaling \$25,000. Please submit a check or money order made payable to the Kansas Board of Pharmacy and include your case number in the check memo.

If you disagree with the findings of fact, you have the right to request a hearing. Instructions for filing a written request are included under the "Notices" section of the order. Hearings are held before the full Board during their regularly scheduled quarterly meetings.

According to KSA 65-1627h, the Board is required to recoup the costs of administrative hearings when the decision is adverse to the licensee. These costs may include charges for services rendered by the Board's disciplinary counsel, an administrative law judge, and, if applicable, a court reporter.

If you have any questions, feel free to contact the Board at Pharmacy.Compliance@ks.gov.

Sincerely,

Kansas Board of Pharmacy

Enclosure

cc:
see next page

800 SW Jackson St., Suite 1414
Topeka, KS 66612



Phone: (785) 296-4056
Fax: (785) 296-8420
pharmacy@ks.gov
www.pharmacy.ks.gov

Alexandra Blasi, Executive Secretary

Laura Kelly, Governor

cc:

Stryker Corporation
6300 S Sprinkle Rd
Portage MI 49002

Stryker Corporation
1941 Stryker Way
Portage MI 49002

Stryker Corporation
5900 Optical Ct
San Jose CA 95138

Stryker Corporation
Stryker Communications, Inc.
571 Silveron Blvd
Flower Mound TX 75028

Mako Surgical Corp
3365 Enterprise Ave
Weston FL 33331

BEFORE THE KANSAS STATE BOARD OF PHARMACY

| | | |
|--|---|-----------------|
| In the Matter of |) | |
| |) | Case No. 24-255 |
| Howmedica Osteonics Corporation |) | |
| dba Stryker Spine (Allendale, NJ) |) | |
| Registration # 4-122812 |) | |
| |) | |
| Stryker Corporation (Portage, MI) |) | |
| Registration # 5-122838 |) | |
| Registration # 4-122878 |) | |
| |) | |
| Stryker Corporation (San Jose, CA) |) | |
| Registration # 5-122884 |) | |
| Registration # 4-122899 |) | |
| |) | |
| Stryker Corporation (Flower Mound, TX) |) | |
| Registration # 5-122879 |) | |
| Stryker Communications, Inc. |) | |
| Registration # 4-122883 |) | |
| |) | |
| Mako Surgical Corp (Weston, FL) |) | |
| Registration # 5-122773 |) | |
| Registration # 4-122772 |) | |

SUMMARY ORDER

NOW, on this 3rd day of September 2024, comes before the Kansas Board of Pharmacy (the “Board”), through its Executive Secretary, the matter of Stryker Corporation ("Applicant"), for application for registration as a manufacturer and a wholesale distributor in the state of Kansas.

Pursuant to the authority granted to the Board by the Kansas Pharmacy Act, K.S.A. 65-1625, *et seq.*, and in accordance with the provisions of the Kansas Administrative Procedure Act, K.S.A. 77-501, *et seq.*, the Board enters this Summary Order in the above-captioned matter. After reviewing the application materials and being otherwise duly advised in the premises, the Board makes the following findings, conclusions, and order:

FINDINGS OF FACT

1. On April 9, 2024, the Board received Applicant’s application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility “Howmedica Osteonics Corporation dba Stryker Spine” located at 2 Pearl Court, Allendale, New Jersey (“Applicant’s NJ Manufacturer Application”).

- a. On Applicant’s Non-Resident Supplemental S-350 form, Applicant answered “Yes” to the following question: “Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months.” The form directs that if the applicant answered “yes,” the applicant should provide the specific drugs and/or devices sent in, the dates of shipment, and the locations they were sent in Kansas.”
- b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 166 unique days from October 4, 2022 to October 31, 2023.

2. On April 11, 2024, the Board received Applicant’s application for registration as a non-resident wholesale distributor in the State of Kansas for the distribution facility “Stryker Corporation” located at 6300 S Sprinkle Road, Portage, Michigan (“Applicant’s MI Distributor Application”).

- a. On Applicant’s Non-Resident Supplemental S-350 form, Applicant answered “Yes” to the following question: “Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months.”
- b. On June 12, 2024, Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 231

unique days from May 24, 2023 to May 23, 2024.

3. On April 19, 2024, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility "Stryker Corporation" located at 1941 Stryker Way, Portage, Michigan ("Applicant's MI Manufacturer Application").

- a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."
- b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 115 unique days from October 7, 2022 to October 3, 2023.

4. On April 19 and 23, 2024, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas ("Applicant's CA Manufacturer Application") and Applicant's application for registration as a non-resident wholesale distributor ("Applicant's CA Distributor Application") for the facility "Stryker Corporation" located at 5900 Optical Court, San Jose, California.

- a. On Applicant's Non-Resident Supplemental S-350 form, Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."
- b. Applicant provided requested copies of shipping records for products shipped into Kansas from January 3, 2023 to March 3, 2024.

5. On April 19, 2024, the Board received Applicant's application for registration as a non-resident wholesale distributor in the State of Kansas for the distribution facility "Stryker

Corporation” located at 571 Silveron Blvd, Flower Mound, Texas (“Applicant’s TX Distributor Application”).

- a. On Applicant’s Non-Resident Supplemental S-350 form, Applicant answered “Yes” to the following question: “Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months.”
- b. Applicant provided requested copies of shipping records for products shipped into Kansas from January 4, 2023 to March 6, 2024.

6. On April 19, 2024, the Board received Applicant’s application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility “Stryker Communications, Inc.” located at 571 Silveron Blvd, Flower Mound, Texas (“Applicant’s TX Manufacturer Application”).

- a. On Applicant’s Non-Resident Supplemental S-350 form, Applicant answered “Yes” to the following question: “Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months.”
- b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 116 unique days from January 11, 2023 to March 6, 2024.

7. On April 1, 2024, the Board received Applicant’s application for registration as a non-resident wholesale distributor in the State of Kansas for the distribution facility “Mako Surgical Corp” located at 3365 Enterprise Ave, Weston, Florida (“Applicant’s FL Distributor Application”).

- a. On Applicant’s Non-Resident Supplemental S-350 form, Applicant answered “Yes” to the following question: “Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months.”

b. Applicant provided requested copies of shipping records for products shipped into Kansas. Applicant reported shipping into Kansas on 132 unique days from August 31, 2022 to August 31, 2023.

8. On April 1, 2024, the Board received Applicant's application for registration as a non-resident manufacturer in the State of Kansas for the manufacturing facility "Mako Surgical Corp" located at 3365 Enterprise Ave, Weston, Florida ("Applicant's FL Manufacturer Application"). Applicant answered "Yes" to the following question: "Has the facility listed on the application shipped drugs and/or devices into Kansas in the previous 12 months."

CONCLUSIONS OF LAW

1. Pursuant to K.S.A. 65-1658, the Board may assess a civil fine not to exceed \$5,000, after notice and an opportunity to be heard, to any registrant for violation of the pharmacy act of the state of Kansas or any other rules or regulations of the state board of pharmacy.

2. Pursuant to K.S.A. 65-1627(f), the Board may take action against the application of any manufacturer or wholesale distributor upon a finding that the applicant has violated the pharmacy act of the state of Kansas or any regulation adopted by the Board.

3. Pursuant to K.S.A. 65-1643(c), it shall be unlawful for any person to distribute at wholesale any drugs or devices without first obtaining a registration from the Board.

4. Pursuant to K.S.A. 65-1643(g), it shall be unlawful for any person to manufacture any drugs or devices without first obtaining a registration from the Board.

5. Applicant's act of shipping into Kansas as a non-resident wholesale distributor from five unique facilities prior to being registered as a wholesale distributor is a violation of K.S.A. 65-1643(c) and is a basis to take action against Applicant's NJ Distributor Application, Applicant's MI Distributor Application, Applicant's TX Distributor Application, Applicant's CA Distributor

Application, and Applicant's FL Distributor Application pursuant to K.S.A. 65-1627(f).

6. Applicant's act of operating as a non-resident manufacturer in Kansas from five unique facilities prior to being registered as a manufacturer is a violation of K.S.A. 65-1643(g) and is a basis to take action against Applicant's NJ Manufacturer Application, Applicant's MI Manufacturer Application, Applicant's TX Manufacturer Application, Applicant's CA Manufacturer Application, and Applicant's FL Manufacturer Application pursuant to K.S.A. 65-1627(f)(6).

ORDER

Based upon the foregoing findings of fact and conclusions of law, Applicant's NJ Distributor Application, Applicant's MI Distributor Application, Applicant's TX Distributor Application, Applicant's CA Distributor Application, Applicant's FL Distributor Application, Applicant's NJ Manufacturer Application, Applicant's MI Manufacturer Application, Applicant's TX Manufacturer Application, Applicant's CA Manufacturer Application, and Applicant's FL Manufacturer Application are hereby GRANTED but Applicant is ordered to pay a fine to the Board in the amount of \$25,000. Applicant has 30 days from the date of this order to pay the fine and the registrations shall be issued upon receipt.

NOTICES

Respondent is hereby notified as follows:

1. Respondent may request a hearing pursuant to the Kansas Administrative Procedure Act by filing a written request with the Kansas Board of Pharmacy, 800 SW Jackson, Suite 1414, Topeka, KS 66612-1231, within 15 days after service of this Order. If the outcome of the hearing is adverse to Respondent, costs of the proceedings shall be charged to Respondent.

2. If a hearing is not requested as described above, the Order shall become a final order of the Board, effective upon the expiration of the time to request a hearing.

3. Within 15 days after entry of a final agency order, either party may file a petition for reconsideration pursuant to K.S.A. 77-529.

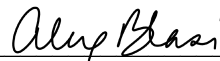
4. Within the time limits established in K.S.A. 77-613, either party may seek judicial review of a final agency order, pursuant to K.S.A. 77-613. The agency officer designated to receive service of a petition for judicial review is:

Alexandra Blasi
Executive Secretary
Kansas Board of Pharmacy
800 SW Jackson, Suite 1414
Topeka, KS 66612

IT IS SO ORDERED.

9/1/2024

Date



Alexandra Blasi, JD, MBA
Executive Secretary
Kansas Board of Pharmacy

CERTIFICATE OF SERVICE

I hereby certify that I did, on the 3rd day of September 2024, deposit in business mail a copy of the foregoing Summary Order, which is then placed in the United States Mail, postage prepaid, properly addressed to the following:

Howmedica Osteonics Corporation
dba Stryker Spine
2 Pearl Ct
Allendale NJ 07401

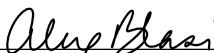
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Kansas Board of Pharmacy Staff