Republic of the Philippines
Department of Health
FOOD AND DRUG ADMINISTRATION

15 FEB 2023

FDA ADVISORY
No. 2020-1811-A

TO: **ALL HEALTHCARE PROFESSIONALS AND THE GENERAL PUBLIC**

SUBJECT: **Lifting the Advisory of the following Medical Device Products under FDA Advisory No. 2020-1811 entitled "Public Health Warning Against the Purchase and Use of the Unregistered Medical Device Products"**

1. **Polaris™ Loop – Dual Durometer Percuflex™ Material - Ureteral Stent (Product No. M0061552440)**
2. **Contour VL™ – Soft Percuflex™ Material – Variable Length Ureteral Stent (Product No. M0061801570)**

The Food and Drug Administration (FDA) informs all healthcare professionals and the general public that the advisory on the following medical device products under FDA Advisory No. 2020-1811 dated 05 October 2020 is hereby lifted pursuant to the compliance of the Market Authorization Holder (MAH) Boston Scientific Philippines, Inc. in accordance to existing FDA rules and regulations.

1. Polaris™ Loop – Dual Durometer Percuflex™ Material - Ureteral Stent (Product No. M0061552440)
2. Contour VL™ – Soft Percuflex™ Material – Variable Length Ureteral Stent (Product No. M0061801570)

The provisions of FDA Advisory No. 2020-1811 indicating unregistered medical device product is still in effect.

The issuance of this advisory shall not in any manner preclude this Office from issuing subsequent orders it may deem necessary and appropriate, should there be findings of any violation of the company to the existing laws, rules, and regulations.

For more information and inquiries, kindly contact the FDA Center for Device Regulation, Radiation Health, and Research through e-mail at **cdrrhr@fda.gov.ph** or call **(02) 8857-1900 loc. 8301.**

To report any sale or distribution of unregistered medical device, contact the online reporting facility, **eReport**, through e-mail at **ereport@fda.gov.ph**.

Dissemination of this advisory to all concerned is hereby requested.

DR. SAMUEL A. ZACATE
Director General

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