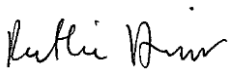
「Sofwave system」 Its Usage status over the world (As of October, 2020)

The status of the approval Acquirement for the device over the countries	The Sofwave system has the following approvals: USA- FDA 510K EU- CE Mark Israel- AMAR approval.
The list of serious side effects could possibly induce by the usage of the device as noted on its instruction for use. (If None, list the information used when applied to FDA)	Adverse events as per the user manual: Anticipated adverse events of ultrasound-based treatment include significant pain, tenderness, changes in skin pigmentation, persistent erythema and edema, ulceration/erosion/or bruising and possible scarring.
Total number of the device delivered over the world.	Install Base: 89 systems.
Total number of patients or treatment cases	>1000 patients
The Side effect report (cases that are reported to the MHLW)	No adverse events were reported
The Manufacturer	Sofwave Medical Ltd Beit Tavor 2 Yokneam Ilit, 2069202 Israel

Name of the company: SofWave Medical

Signature and date: Ruthie Amir, MD, CMO, SofWave Medical, January17,2021



※日本語訳

2020 年 10 月時点

機器名	Sofwave
機器の欧米各国における承認取得情報	米国-FDA 510K 取得 EU-CE マーク取得 イスラエル-AMAR 取得
機器の添付文書に掲載している重大な副作用一覧　（ない場合、FDA など承認取得時の内容）	著しい痛み 圧痛 皮膚の色素沈着 持続性の紅斑および浮腫 潰瘍形成/びらん/あざ 瘢痕形成
機器の世界における納入台数	89 台
累計患者数または治療数	1000 例以上
副作用報告（各国の厚生労働省などに提出しているもの）	報告なし
製造元	Sofwave Medical Ltd （イスラエル）