「Spark Pro 」 Its Usage status over the world(As of AUGUST 2021)

The status of the approval Acquirement for the device over the countries	Israel approved by MOH 2019, United States approved by FDA on 2018, EU approved on 2018, Singapore, Ecuador and so on are undergoing registration procedure.
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)	As appears in the IFU and submitted to the FDA Erythema (redness) Edema (swelling) Discomfort/ pain Hyper/Hypo pigmentation Irritation Superficial burns Scab formation Scarring • • • • • • • •
Total number of the device delivered over the world.	Grand Total 630 Systems
Total number of patients or treatment cases	We don’t have such information.
The Side effect report (cases that are reported to the MHLW)	None was reported
The Manufacturer	Formatk Systems Ltd. 3 hayozma St., Tirat Hacarmel, 3903203, Israel

Name of the company: Formatk systems LTD Signature and date: 23rd of August 2021

※日本語訳

機器名	Spark pro
機器の欧米各国における承認取得情報	イスラエル（2019)、米国・EU（2018)、シンガポール・エクアドル他は申請中。
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）	紅斑、浮腫、不快感、痛み、色素沈着、色素低下、刺激感、表在性火傷、かさぶたの形成、傷跡
機器の世界における納入台数	630 台以上
累計患者数または治療数	情報なし
副作用報告（各国の厚生労働省などに提出しているもの）	なし
製造元	Formatk Systems Ltd.（イスラエル）