

EOPatch's Smartphone Application 'Narsha' gets Korean MFDS Approval

World's first commercial smartphone app to deliver insulin for wearable pump
Satisfies all cyber security requirements from Korean MFDS

▶ EOFlow's first wearable insulin pump, EOPatch will officially launch in Korea on the 29th

<u>On March 24, EOFlow, a provider of wearable drug delivery solutions, has announced that 'Narsha,' a smartphone application for wearable insulin delivery, obtained medical device</u> approval from the Ministry of Food and Drug Safety (MFDS) on the 23rd.

Narsha is a smartphone application(hereinafter referred to as an app) that can monitor and control insulin injection of a tubeless, wearable 'EOPatch'. Narsha is known to be the world's first commercially approved app that controls insulin injection from a wearable pump. Narsha can also communicate with a separate continuous glucose monitoring sensor(CGMS) to monitor blood glucose level. Currently Narsha can connect with Dexcom's G6 glucose sensor.

The existing EOPatch insulin management system consists of a wearable insulin pump 'Patch,' a smartphone like controller 'ADM,' and a diabetes management software 'EOBridge.' A Patch and an ADM work together to control insulin injections, and up to 90 days' injection history is stored. Data is synchronized to the EOBridge app or web to be analyzed and shared with guardians or medical personnel.

Even though ADM is a convenient, portable smartphone like device, there was a great need for an app development. An EOFlow official said, "We expect that Narsha app will greatly improve user convenience by eliminating the need to carry a dedicated controller. Also, Narsha has more advanced screen design which brings improved usability."

Cyber security is essential with devices like ADM or Narsha app which connects to an insulin injector via Bluetooth. If the device is vulnerable to security, there is a cyber security threat, it can be hacked and causes malfunction, personal medical information may be stolen, and a user's health may be seriously threatened if there is any insulin injection abuse.

"Narsha has met all the cyber security requirements of a medical device set by the Korean Ministry of Food and Drug Safety," an EOFlow official said. "In addition, there is no large cost to download an app from an app store, so it is very economical that high demand in the market is expected."

EOFlow plans to fully launch its first wearable insulin pump, EOPatch in Korea on March 29th. The initial launch will be with ADMs only. Narsha app will be released in about two months after user manuals and educational materials are prepared.