Blisters are pockets of fluid in the skin that are commonly caused by friction, or rubbing of the skin for long periods of time. In those with greater disease severity and urate burden, such as those with tophi, guidelines recommend lowering SUA to 5.0 mg/dL (300 mmol/L) to achieve better disease control. This can be done if the manufacturer can prove that the medical device is significantly similar to an existing FDA-approved device.