

K961287



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Rocketmedical

Summary of Safety and Effectiveness

Pleuraseal III Chest Drainage System

This device has been designed to allow the safe and effective drainage of fluid from a patient following disruption in the normal anatomical arrangement of the chest or a disturbance of the intrapleural pressure mechanism causing the entry and accumulation of air and or fluid.

This is achieved by a design incorporating safety features to maintain a constant suction pressure, prevent the ingress of air and fluid back into the chest cavity, whilst maintaining an unobstructed drain from the patient.

This is a class II device, registered by Rocket Medical (Establishment number: 8010022/9610632). This device is substantially equivalent to a medical device which is currently in commerce and has been submitted to the FDA, marketed by Atrium.

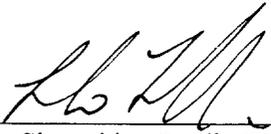
The device is safe and effective for the application for which it is intended and has been tested to confirm its safety and effectiveness for over 1 year, without incident in the UK.

Rocket Medical continues to search all appropriate sources for information relating to safety and effectiveness and maintains an in-house reporting system to identify adverse safety and effectiveness information and as such, applicable data is recorded for this product.

CERTIFICATION

I hereby certify that this Summary of Safety and Effectiveness applies for the above indicated device.

27th March 1996
Date


Signed by Leslie Todd
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