Tom Thumb without Clinical Trial Data

The Tom Thumb has not been subjected to Clinical trials as defined in Annexe 10 and was placed on the market prior to the introduction of the CE mark and associated procedures

Placed on the market 1993	YES NO
Grandfather product	NO
Equivalent to other products on the market	YES Fisher Paykel Neopuff

The product is a gas flow control system using the thumb to divert flowing gas into a Neonates lungs. It was designed and used by Clinicians to replace the bag and mask method of hand ventilation, It consists of a Tee valve and, a pressure gauge a adjustable blow off valve and a safety valve
Optional Flow meters are available

1. Benefit /risk of the device
   This device replaces the need to bag patients, It therefore allows the operator to control the time of positive ventilation whilst reducing the fatigue factor.
   The inclusion of a gauge and a blow of valve increases patient safety
2. Equivalence to other devices on the market
   There are several devices now available
3. Demonstration of acceptability to harmonised standards
   Full CE Technical file available
4. The “state of the art”
   This device is manufactured out of chromed brass. It appears to have an unlimited life
5. Post market surveillance data on device performance
   Changes have been made to the diameters of the ventilation tube fittings,
   Where requested restrictions to protect the gauge have been fitted
6. Vigilance reports
   There have been incidents with this device but all have been traced to user error and cleared by the MHRA
7. Registry data
8. Maintenance history
   The only components requiring maintenance are the O rings.
9. Sales/marketing feedback
   The unit is in the progress of being boxed for aesthetic reasons only. The original version is open and modular in construction allowing many different ways of mounting
10. User feedback.
    User feedback has been very restricted and apart from the changing of the tube diameters has not promoted any product changes.