Tom Thumb Clinical evaluation

1.	General Details	
1.1	State the proprietary name of the device	Tom Thumb
1.2	Any code names assigned during device development.	N/A Developed 25 Years ago
1.3	Identify the manufacturer (s) of the device.	Viamed Ltd
2.	Description of the device and its intended application	The Tom Thumb is an infant resuscitation unit, designed to replace the manual ventilation by the bag, mask and valve method. It is intended for use in emergency resuscitation situations such as delivery rooms, operating theatres and special baby care units. It is designed to control a flow of gas from an external source. The flow being controlled, by the operator occluding one leg of a Tee on the mask, instead of the original and usually uneven method of bag compressions.
2.1	Provide a concise physical description of the device	Tom thumb is a non sterile Brass Block with and Adjustable Blow-off Value, and a safety Value. It is used in conjunction with a T Occluder breathing circuit
2.2	Cross referencing to relevant sections of the manufacturer 's technical information as appropriate	
2.3	The description should cover information such as:	
2.4	materials	Tom thumb is a non sterile Brass Block with and Adjustable Blow-off Value, and a safety Value. It is used in conjunction with a T Occluder breathing circuit
2.5	whether it incorporates a medicinal substance	No medical substances
2.6	(already on the market or new	Been on the market in its current from since : 1984
2.7	tissues	N/A

2.8	blood products;	N/A
2.9	The device components, including software and accessories;	Only accessory component is the T Occluder breathing circuit
2.10	mechanical characteristics;	Tom thumb is a non sterile Brass Block with and Adjustable Blow-off Value, and a safety Value.
2.11	others, such as sterile vs. non-sterile,	Non Sterile
2.12	radioactivity etc.	N/A
2.13	State the intended application of the device	The Tom Thumb is an infant resuscitation unit, designed to replace the manual ventilation by the bag, mask and valve method. It is intended for use in emergency resuscitation situations such as delivery rooms, operating theatres and special baby care units. It is designed to control a flow of gas from an external source. The flow being controlled, by the operator occluding one leg of a Tee on the mask, instead of the original and usually uneven method of bag compressions.
2.14	Single use	Not Single Use
2.15	Re-useable	Yes
2.16	invasive/non invasive	Non invasive
2.17	Implantable duration of use or contact with the body; organs, tissues or body fluids contacted by the device.	Tom thumb itself has no contact with the patient,
2.18	Describe how the device achieves its intended purpose.	Tom thumb is a non sterile Brass Block with and Adjustable Blow-off Value, and a safety Value.
3	3. Intended therapeutic and/or diagnostic indications and claims	The are no therapeutic / diagnostic or indications.
3.1	State the medical conditions to be treated.	Premature Birth / Difficult birth - requiring breathing assistance

	including target treatment group and diseases.	
3.2	Outline any specific safety or performance claims made for the device	Maximum pressure.
4	4. Context of the evaluation and choice of clinical data types	The Tom thumb has been in use since 1990, it has various competitor devices (Neo Puff). IT is a well establish product, and clinical papers eg. “Use of self-inflating bags for neonatal resusitation' often refer to the T occluder method of resusitation as the Tom Thumb Method
4.1	Outline the developmental context for the device. The information should include whether the device is based on a new technology, . The amount of information will differ according to the history of the technology. Where a completely new technology has been developed, this section would need to give an overview of the developmental process and the	Uses the basic physics principle of the Tee occluder. I.e gas will choose the line of least resistance. Has been used as the basis for Neonatal ventilation since the early 1970's Bourns, Drager, Sechrist. SLE etc. Simple Tee occluders include IMI , F&P Neopuff, Clinical data is for all devices. The variations are in the electronic control of inspiration/expiration times (controlled manually in the Tom Thumb).

	points in the development cycle at which clinical data have been generated. For long standing technology, a shorter description of the history of the technology (with appropriate references) could be used. Clearly state if the clinical data used in the evaluation are for an equivalent device.	
4.2	a new clinical application of an existing technology,	Established application since 1990
4.3	or the result of incremental change of an existing technology	
4.4	Identify the equivalent device(s) and provide a justification of the equivalency, cross-referenced to the relevant non-clinical documentation that supports the claim.	E 5.3 Competitive literature and papers
4.5	State the Essential Requirement	Maximum Pressure, Maximum Pressure set to 45Cmh2O as per ISO 10651-4:

	s relevant to the device in question, in particular, any special	
4.6	design features that pose special performance or safety concerns (e.g. presence of medicinal ,human or animal components) that were identified in the device risk management documentation and that required assessment from a clinical perspective.	Maximum Pressure, Maximum Pressure set to 45Cmh2O as per ISO 10651-4:
4.7	Outline how these considerations were used to choose the types of clinical data used for the evaluation. Where published scientific literature has been used, provide a brief outline of the searching/retrieval process, cross-referenced to the literature search protocol and reports.	
5	5. Summary of the clinical data and appraisal	

5.1	Provide a tabulation of the clinical data used in the evaluation, categorised according to whether the data address the performance or the safety of the device in question. (Note: many individual data sets will address both safety and performance.) Within each category, order the data according to the importance of their contribution to establishing the safety and performance of the device and in relation to any specific claims about performance or safety.	Oxford Desk Reference: Obstetrics and Gynaecology By Sabaratnam Arulkumaran, Lesley Regan, Aris Papageorghiou, Ash Monga, David Farquharson Page 414, N Kennea & S Ali "These breaths are given using a bag and mask, or preferably a pressurelimited Tom Thumb' or other ventilation device." Published by Oxford University Press in 23rd June 2011 Neonatal Resuscitation - Infant volume 6 issue 1 2010 . Please see the attached review of neonatal resuscitation at the Royal Victoria Infirmary, written by: Specialist Registrar, Charge Nurse, Staff Nurse, Consultant Neonatologist: Newcastle Neonatal Service, Ward 35, Royal Victoria Infirmary, Newcastle. "This resuscitaire has been customised to deliver blended air and oxygen, PIP and PEEP through the use of a Tom-Thumb blow off system with a PEEP valve integrated into the circuit (FIGURE 3). A flow restrictor minimises the risk of inadvertent PEEP administration. These customisations were made in an attempt to protect the newborn from the injurious effects of lack of PEEP or excess oxygen.". Obstetric and Intrapartum Emergencies: A Practical Guide to Management By Edwin Chandraharan, Sabaratnam Arulkumaran ... healthy babies who received no resuscitation or supplemental oxygen within a ... or preferably a pressure-limited T piece, `Tom Thumb` or other ventilation device Cambridge University Press Children and Young People`s Nursing at a Glance .. T-piece circuit; Tom Thumb or T-piece device • Self-inflating bag (500 mL) with ... Edited by Alan Glasper, Jane Coad, Jim Richardson Published by Wiley
5.2	Additionally, provide a brief outline of the data appraisal methods used in the evaluation, including any weighting criteria, and a summary of the key results.	Google

5.3	Include full citations for literature-based data and the titles and investigation codes (if relevant) of any clinical investigation reports.	
5.4	Cross-reference the entry for each piece of data to its location in the manufacturer's technical documentation.	
	6. Data analysis	
6.1	Performance	
6.1.1	Provide a description of the analysis used to assess performance.	25 Years of sales,
6.1.2	Identify the datasets that are considered to be the most important in contributing to the demonstration of the overall performance of the device and, where useful, particular performance characteristics.	
6.1.3	Outline why they are considered to be "pivotal"	

	and how they demonstrate the performance of the device collectively (e.g. consistency of results, statistical significance, clinically significance of effects).	
6.2	Safety	
6.2.1	Describe the total experience with the device, including numbers and characteristics of patients exposed to the device; and duration of follow-up of device recipients.	25 Years of Sales 100-200 per
6.2.2	Provide a summary of device-related adverse events, paying particular attention to serious adverse events.	There are NO device related adverse events
6.2.3	Provide specific comment on whether the safety characteristics and intended purpose of the device requires training of the end-user.	Yes – Training to established hospital protocols

6.3	Product Literature and Instructions for Use	
	State whether the manufacturer 's proposed product literature and Instructions for Use are consistent with the clinical data and cover all the hazards and other clinically relevant information that may impact on the use of the device.	L 1 Promotional literature F 5 Instructions for use
	7. Conclusions	
7.1	Outline clearly the conclusions reached about the safety	The device has been on the market since 1993. It was designed under the guidance of Professor Lister Princess Mary Hospital Newcastle who's prototypes manufactured by Medical Physics had been successfully used to resuscitate neonates for several years. The Tom Thumb has been used continuously and successfully without major failure
7.2	and performance of the device from the evaluation, with respect to the intended use of the device.	T - Occluder devices are still the recommended method of infant resuscitation as compared to the other Bag and Mask method of resuscitation for newborns
7.3	State whether the risks identified in the risk management documentation have been addressed by the clinical data.	
7.4	For each proposed clinical indication state	

	whether:	
7.5	the clinical evidence demonstrates conformity with relevant Essential Requirements;	C 1 Essential requirements
7.6	the performance and safety of the device as claimed have been established; and	Yes safety record
7.7	the risks associated with the use of the device are acceptable when weighed against the benefits to the patient	Risk ID11 : is special intervention necessary in the case of failure of the medical device ID59 : Patient Environment with regard to pressure Both the Main value and the safety value would have to fail and the user would have to revert to a bag and mask resuscitator, or find a replacement resuscitator. Routine maintenance of the device this likely hood of either value failing is unlikely. DOC ID:15008 DOC ID:2209 Risk ID105 : Factors that should be considered include any restrictions placed upon users in their selection of accessories. Using a circuit with the T Occluder, Maximum pressure would be 45cmH20 as required by ISO 10651-4, Operator should immediately be aware they are using the device incorrectly as there will not be the T Occluder for them to use the resuscitator Risk ID153 : Is the medical device used in an environment where distractions can cause use error Factors that should be considered include the consequence of use error : Used in maternity, level environment distractions will be High, however the number one patient will be the infant if the Tom Thumb is in use.