

FDA & MEDICAL DEVICES IN PEDIATRICS

Introduction

Fisher & Paykel Healthcare Limited is a designer and manufacturer of a range of innovative healthcare devices which incorporate unique features to improve patient care.

Our headquarters, research and development and manufacturing facilities are based in New Zealand. Fisher & Paykel Healthcare have sales and marketing operations throughout the world, with North America and the EU being major sales locations.

We operate principally in the growing respiratory; sleep disordered breathing, critical care and operating room markets. Our products currently include respiratory humidifiers, breathing circuits and accessories, CPAP devices for the treatment of obstructive sleep apnea (OSA) and radiant warmers, infant resuscitators and accessories.

Fisher & Paykel Healthcare hold certification to ISO 13485:2003 "Medical devices – Quality Management systems – Requirements for regulatory purposes" issued by TÜV Product Services (an EU Notified Body). Market clearances for our devices in the US are sought primarily via the 510(k) process, which are designed in compliance with the QSR. We CE mark and sell medical devices to EU via Annex II (Declaration of Conformity except EC Design Examination) of MDD 93/42/EEC.

Current Interest & Experience

Fisher & Paykel Healthcare Limited have a current interest in improving access of medical devices to the pediatric population in all three areas of its business. Our experience with the FDA regarding device usage in pediatric populations is varied across the 3 businesses.

In the Respiratory business we design and market globally a range of neonatal breathing circuits. At present we only sell two of these neonatal circuits to the United States market. We are going through the 510(k) process for another two neonatal circuits.

The Neonatal division have designed and developed a CPAP device based upon a therapy that has been used in hospitals in the USA for a very long period of time. The device is specifically for newborns. This device is currently going through the regulatory approval process in the USA. There has been difficulty with this submission due to the fact that the FDA does not regard the current device as a predicate (even though US hospitals regard the therapy as standard of care).

OSA design and develop medical devices for the treatment and prevention of obstructive sleep apnea in adults. Extension of the indication to include use in pediatrics is currently being explored.

Current FDA Status

The FDA has come some way in encouraging the development and regulatory approval of devices for use in pediatrics.

There has been one guidance document put out by the FDA on pediatric devices – “Premarket Assessment of Pediatric Medical Devices” (14 May 2004).

With the onset of MDUFMA, 510(k)'s and PMA's for pediatric devices are at no cost.

From our experience, the review times for a pediatric device and for an adult device are of an equivalent length of time.

(1) What are the unmet medical device needs in the pediatric population (neonates, infants, children and adolescents)? Are they focused in certain medical specialities and/or pediatric subpopulations?

We have no comment to make regarding this question.

(2) What are the possible barriers to the development of new pediatric devices? Are there regulatory hurdles? Clinical Hindrances? Economic issues? Legal issues?

We have identified the following possible barriers to the development of new pediatric devices:

Regulatory:

- The review of a pediatric medical device may invoke an emotional response from the FDA reviewers resulting in judgement being clouded
- In the review of a submission of a pediatric medical device, the risk level of the device is considered to be greater and more documentation/evidence is required.
- There does not seem to be consistency in the regulatory requirements applied for an medical device that is to be used in adults and for a medical device that is for pediatrics

Clinical:

- IDE approval by an Institutional Review Board is harder and takes longer for a clinical trial in a pediatric population
- The pediatric population is a smaller group making it harder to get the numbers required in a clinical trial. This increases the length of time before the company is able to gain any return on their investment in product development
- An ill child is an emotional stress for any parent. There may be some reluctance to try a new medical device on your already sick child. This makes parental consent, recruitment and follow-up more difficult

Economic:

- Pediatric trials are more expensive to set up (IDE approval is a longer process); they take longer to run (to get significant numbers the trial must run for longer to recruit sufficient patients from a limited patient population); and therefore limit the return the company can obtain from the device
- For example, newborns with a very low birth weight (between 500 – 1500 g) represent approximately 0.5-1% of all live births in the USA. This is a market with a small commercial return. The costs associated in clearance to market in this population are large. The population available to conduct clinical trials is small so

any trials will last for an extended period of time. Additionally, there is no sale premium associated with pediatric devices

- This leads to companies questioning the financial viability of running trials to gain a pediatric indication. In turn, this leads to the use of the product by doctors and consumers in an off-label manner

(3) What could the FDA do to facilitate the development of devices intended for the pediatric population? Are there changes to the law, regulation, or premarket process that would encourage clinical investigators, sponsors and manufacturers to pursue clinical trials and/or marketing of pediatric devices?

We have identified the following areas that may encourage the pediatric approval of medical devices:

Regulatory:

- Expand the definition of predicate device – Are the FDA prepared to accept a therapy or a custom-made device (not distributed commercially) as a predicate device when that device (and the therapy it employs) is considered by medical professionals to be “standard-of-care”? For example, what about devices that deliver therapy that are considered best practice?
- Streamline the *de novo* 510(k) application.
Currently a 510(k) must be submitted, evaluated, and determined to be “Not substantially equivalent” (NSE), Class III, before a *de novo* 510(k) request can be made.
This process is too long for manufacturers. Why can’t manufacturers have the option of submitting a *de novo* 510(k) right from the start?
- Publicise the *de novo* 510(k) option to manufacturers
- Allow on-line applications for pediatric submissions
- More guidance from the FDA on specific pediatric submissions and the options available to industry in gaining approval
- Develop an additional 510(k) process for a pediatric device or a paediatric extension (traditional; special; abbreviated; pediatric, etc)
- Apply consistency of the level of evidence required for an pediatric device compared to an adult device
- Reduce review time for new pediatric devices / pediatric extension of existing devices

Clinical:

- Define further the level of consent required. Perhaps the level of parental consent required correlates with the type of new device i.e., a new type of breathing circuit from a company with a confirmed history of selling breathing circuits in the USA may need a different level of parental consent than a company with no history.
- The FDA need to more readily accept pediatric trials from the EU and other developed countries. The FDA should work with industry to explain the ways in that the EU clinical trials need to be run to satisfy the FDA requirements.
- Acceptance/acknowledgement of experience/approval of the device from other developed countries with recognised device regulation and design controls i.e., EU, Canada, Japan, Australia

Economic:

- Currently a 510(k) for a pediatric device is free. What about giving the option to companies of having an expedited 510(k) review if they pay a fee?

Other:

- Education and guidance from the FDA to doctors, health professionals, consumers and manufacturers on the possible consequences of the use of a device off-label and advertising an off-label use (on websites, etc).

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Yours sincerely



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