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SELECT MEDICAL SYSTEMS INC.

Food and Drug Administration
Center For Devices and Radiological Health (HFZ-401)
9200 Corporate Boulevard
Rockville MD 20850

MAR 23 1998 510(k)Summary

Submitter	Select Medical Systems, Inc 2 Winter Sport Lane P.O. Box 966 Williston VT 05495-0966 Ph (802) 862-1017 Fx (802) 862-3767
Contact person	Monique Girard
Date of Summary	12-22-97 MM DD YY
Device proprietary name	SelectCells™Mini
Device common name	Endometrial sampling device
Device classification name	Endometrial suction curette (per 21 CFR section 884.1175)
Predicate device name	Pipelle®

This summary of 510(k) safety and effectiveness information is being submitted in accordance with the requirements of SMDA 1990 and 21 CFR 807.92(c).

Intended use

Same as the Pipelle® (predicate device), the SelectCells™Mini (new device) is a single use, sterile, disposable endometrial sampling device designed to be used for obtaining a histologic biopsy of the uterine mucosal lining or specimen of the uterine menstrual content. The specimen obtained is then used for the following: (i) evaluation of infertility conditions, menstrual disorders, postmenopausal bleeding, abnormal cytology suspected of being of endometrial origin, hormonal replacement therapy; (ii) detection of endometrial carcinoma; (iii) diagnosis of luteal defect; (iv) endometrial dating and,(v) microscopic examination.

Description of new device and comparison with predicate device

The SelectCells Mini, like the Pipelle, comprises a long clear, flexible, polypropylene sheath and a rod made of acetal copolymer onto which a piston is molded.

The sheath of the SelectCells Mini is a one part tube whose distal half has a smaller diameter than its proximal half. The sheath of the Pipelle is a one part tube with the same diameter throughout.

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The device opening, by which the specimen is to be aspirated, is located at 2.5 mm distance (3 mm for Pipelle®) from the extreme distal tip of the sheath. The extreme distal end of the sheath is rounded and closed.

A piston is molded on the rod at almost its half length point (piston located at the distal end of the rod for Pipelle). This rod can be moved forward and backward within the proximal half length of the sheath lumen. The piston and rod are prevented from being totally withdrawn from the sheath during manipulation by the tapered proximal lumen end of the sheath (for Pipelle, by an identation in the sheath located at its proximal end).

The new device has an ergonomic 2.5 cm long finger grip which is molded onto the rod that protrudes the proximal end of the sheath. The Pipelle has a cylindrical 2.4 cm long knob which is glued to the rod that protrudes the proximal end of the sheath. This finger grip (knob, for Pipelle) is used to move the rod within the sheath.

The SelectCells™ Mini bears seven (7) coloured graduation marks with figures that are placed at 4, 5, 6, 7, 8, 9, and 10 cm distance from the extreme distal tip of the sheath. The predicate device bears four (4) coloured graduation marks with figures and three (3) marks in the form of a line that are placed at 4, 5, 6, 7, 8, 9 and 10 cm distance from the extreme distal tip of the sheath. The new and predicate devices bear an arrow on their sheaths indicating the location of the device opening. The graduation marks on the sheath serve as a guide for insertion depth of the device into the uterine cavity.

Function of the device

As the Pipelle, the SelectCells Mini is to be used to remove material from the endometrium and from the mucosal lining of the uterine cavity by suctioning. The specimen obtained is then used for histologic biopsy or microscopic examination.

With the patient in position; the uterus is probed for depth and direction with a uterine sound. The uterine cervix lip is grasped with the proper instrument and according to its direction. The cervical curvature is straightened.

The device, with the piston rod fully depressed at the extreme distal end of the sheath, is inserted into the uterus up to the fundus (according to its depth as previously determined).

The piston is moved toward the proximal end of the sheath by pulling the piston rod until it stops. The device is then rotated through 360 degrees while making a gentle "to and fro" movement a few times. This procedure creates a negative pressure inside the sheath aspirating the sample into the sheath lumen through the device opening.

The device is then slowly withdrawn from the uterus. The sample is expelled in a specimen receptacle and sent to the laboratory for analysis.

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Technical characteristics - Comparison summary between new and predicate devices

	SelectCells™ Mini (new device)	Pipelle® (predicate device)
Length	29.8 cm (overall) 25.6 cm (effective)	26.5 cm (overall) 23.5 cm (effective)
I.D. (inner diameter)	1.5 mm (distal 13 cm)	
O.D. (outer diameter)	1.9 mm (distal 13 cm)	
I.D.	2.6 mm (proximal 13.7 cm)	2.6 mm (throughout)
O.D.	3.1 mm (proximal 13.7 cm)	3.1 mm (throughout)

The minor difference in length and smaller distal 13 cm I.D. and O.D. do not affect the function, safety and efficacy of the new device as demonstrated in the Clinical Performance Data below. The new device has been designed with a smaller diameter on its distal portion to ease insertion and increase patient comfort during the procedure.

	SelectCells™ Mini (new device)	Pipelle® (predicate device)
Graduation marks	At 4, 5, 6, 7, 8, 9, and 10 cm distance from the extreme distal tip of the sheath. An arrow indicating location of device opening.	At 4, 5, 6, 7, 8, 9 and 10 cm distance from the extreme distal tip of the sheath. An arrow indicating location of device opening.

The new device bears seven (7) graduation marks with figures as compared to the predicate device which has four (4) marks with figures and three (3) in the form of a line making the graduation marks clearer on the new device than the predicate device.

	SelectCells™ Mini (new device)	Pipelle® (predicate device)
Rod stop mechanism	Proximal sheath end is tapered	Proximal sheath end bears an identation
Rod grip	Molded finger grip	Glued knob
	These differences are minor and reflect only a preference in manufacturing.	
Piston location	At half length on the rod	At distal end of the rod

Because the new device has a smaller diameter on almost half of the sheath distal portion than its proximal portion, the piston had to be molded at half length point on the rod. This difference is minor and safety/efficacy performance of the new device is not affected as demonstrated in the Clinical Performance Data below.

Design	Similar to Pipelle	Similar to SelectCells Mini
Materials	Similar to Pipelle	Similar to SelectCells Mini

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Non-clinical performance data

	SelectCells™ Mini (new device)	Pipelle® (predicate device)
Negative pressure	Average of 20.1 mm of water	Average of 19.3 mm of water

The amount of negative pressure generated by the new and predicate devices was evaluated by an independent testing laboratory. On five sterile specimens of each device, negative pressure data were taken in triplicate using an open-tube water manometer. The sampling end (distal end) of the device was positioned to a designated position ensuring that each specimen was tested with the same amount of head space and displaced volume. A pressure relief valve was then opened to relieve any pressure built up in the system due to insertion of the device. Each measurement was obtained upon device piston rod displacements of ten centimeters. With the relief valve closed, the piston rod was pulled back continuously, until the maximum of ten centimeters on the devices' graduation marking was reached. The difference in the water levels in the manometer was then documented.

The reproducibility of the measurements was found to be very acceptable. Based on the data, it is apparent the negative pressure amount produced by the SelectCells Mini is greater than the negative pressure amount produced by the Pipelle.

These results indicate that the new device generates slightly more negative pressure than the predicate device thus, is able to suction an endometrial specimen as well as the predicate device. The Clinical Performance Data section supports this statement as well.

In conclusion, the results indicate that the new device is substantially equivalent to the predicate device.

	SelectCells™ Mini (new device)	Pipelle® (predicate device)
Tensile force	Average of 13.7 lbs	Average of 13.9 lbs
Tensile strength	Average of 3940 PSI	Average of 4010 PSI
Elongation at break	Average of 364%	Average of 605%

The tensile properties of the new and predicate devices were evaluated by an independent laboratory per ASTM D 638-96. Five sterile specimens of each device were tested. The initial test used a 7" and 6" grip separation for the new device and the predicate device respectively. Due to the elongation properties of polypropylene beyond the limits of the universal tester, testing was performed under modified ASTM D 638-96 by choosing a smaller grip separation of 3.5".

Tensile force results are equivalent because both devices are made of the same material. There is no question regarding safety and efficacy of the new device compared to the predicate device as the results are equivalent. Tensile strength results, which measures a finite point on a cross section of the products, vary by less than 2% and are statistically insignificant. As expected, the new device has one half elongation of the predicate device as its diameter stepped down at its half way point. All breaks in the new device occurred at the region proximal to the change in diameter.

Neither the SelectCells Mini nor the Pipelle are subjected to any tensile force, strength, or elongation while using the product for endometrial sampling.

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Clinical performance data

The safety and efficacy of the new device have been evaluated in a clinical study. To demonstrate that the new device provides an adequate endometrial specimen for a histological biopsy of the endometrium, a blind, controlled, prospective, randomized clinical study has been conducted on 10 patients.

Twelve (12) female patients aged 18 years or older having a clinical indication for endometrial sampling were recruited for the study. Results from two (2) patients were excluded as one patient could not be sampled with either device due to a cervical obstruction while the other patient had inadequate tissue obtained with both devices to evaluate.

Twenty (20) endometrial samplings were performed. Each of the ten (10) patients had her endometrium sampled twice. Five (5) patients were sampled with the new device followed by sampling with the predicate device. The other five (5) patients were sampled with the predicate device followed by sampling with the new device. Each patient served as her own control in order to eliminate any variations from patient to patient as to the sample produced.

No Protocol deviations, adverse events or complications occurred which demonstrate the safety of the new device.

In all ten (10) patients who had successful endometrial samplings, the pathology reports were concordant as to the diagnosis obtained with either sampling device. Results on preservation of histologic detail are comparable from both devices. It appears that the sequence of sampling had an effect but in none of the cases was the difference greater than one grade. As expected, the predicate device produced a larger sample size than the new device. The histologic grade results favor the predicate device but not more than by one and one half grades. These differences in the results do not affect the efficacy of the new device as all the ten patient pathology reports demonstrate concordant diagnoses of paired specimens.

The specimen preservation is uniform throughout the specimens.

The new device provided greater patient comfort than the predicate device. The new device produced less cramping, cervical bleeding, cervical and uterine pain than the predicate device.

Based on the results of the Clinical Study, it can be concluded that the new device is substantially equivalent to the predicate device. The new device performed better than the predicate device in terms of patient comfort and diminished intensity of symptoms produced by the procedure itself.

Substantial equivalence

The intended use, function and technical characteristics along with results obtained from the non-clinical and clinical tests indicate that the new device, the SelectCells™ Mini is substantially equivalent in safety, effectiveness and performance to the predicate device, the Pipelle®.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
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MAR 23 1998

Ms. Monique Girard
Regulatory Affairs Manager
Select Medical Systems, Inc.
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Re: K974819
SelectCells™ Mini (Endometrial Suction Curette and Accessories)
Dated: December 22, 1997
Received: December 23, 1997
Regulatory Class: II
21 CFR 884.1175/Procode: 85 HHK

Dear Ms. Girard:

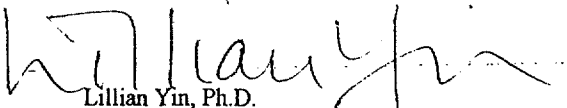
We have reviewed your Section 510(k) notification of intent to market the device referenced above and we have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (Premarket Approval), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 895. A substantially equivalent determination assumes compliance with the Current Good Manufacturing Practice requirements, as set forth in the Quality System Regulation (QS) for Medical Devices: General regulation (21 CFR Part 820) and that, through periodic QS inspections, the Food and Drug Administration (FDA) will verify such assumptions. Failure to comply with the GMP regulation may result in regulatory action. In addition, FDA may publish further announcements concerning your device in the Federal Register. Please note: this response to your premarket notification submission does not affect any obligation you might have under sections 531 through 542 of the Act for devices under the Electronic Product Radiation Control provisions, or other Federal laws or regulations.

This letter will allow you to begin marketing your device as described in your 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4613. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21 CFR 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address "http://www.fda.gov/cdrh/dsma/dsmamain.html".

Sincerely yours,



Lillian Yin, Ph.D.
Director, Division of Reproductive, Abdominal, Ear, Nose and Throat and Radiological Devices
Office of Device Evaluation
Center for Devices and Radiological Health

Enclosure

510(k) NUMBER (IF KNOWN): K974819

DEVICE NAME: SelectCells™ Mini

INDICATIONS FOR USE:

Biopsy to obtain a sample for histologic evaluation of the endometrium (uterine mucosal lining) or sample extraction of the uterine menstrual content for:

- Evaluation of infertility conditions, menstrual disorders, postmenopausal bleeding, abnormal cytology suggesting endometrial origin, hormonal replacement therapy (HRT);
- Detection of endometrial carcinoma (Please note: The most reliable method for the detection of endometrial carcinoma is dilation of the cervix and uterine curettage performed under general anesthesia);
- Evaluation of luteal defect (Evaluation of luteal defect is visually determined histologically from endometrial tissue obtained only during the secretory [progestational] phase of the menstrual cycle);
- Endometrial dating;
- Microscopic examination;
- and, this device is useful for patients presenting a narrow cervix or cervical canal and in postmenopausal women whose cervix might be narrower with any of the indications listed above. However, because of its smaller diameter, it should be recognized that the amount (quantity) of sample obtained with this device will be reduced.

Rev. 1 March 23, 1998

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED.)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ OR Over-The-Counter-Use ____
(Per 21 CFR 801.109) (Optional Format 1-2-96)

Peter R Salling
(Division Sign-Off)
Division of Reproductive, Abdominal, ENT, and Radiological Devices
510(k) Number K974819