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NORTH EOS INDUSTRIES, INC.

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Classification ; EOS Brand Disposable Cyto/Cervical Sampler
Common name ; EosSmear
Brand name ; EOS Brand
Registration ; #8043235
Class I

DATE : AUG.28,1996
REF. :

510(k) SUMMARY

The device has the same intended use and technological characteristics as the legally premarketed devices. Its usage, mode of action are equivalent to the legally premarketed devices.

We indicate devices that premarketed world widely, the devices also called by people among medical fields , like, doctors, nurses, medical traders purchasers of the medical products, etc., they are commonly used in the hospitals for Pap.s.,

And our this device is the same purpose used for Pap.s.as the premarketed devices which we mentioned as followings;

Ayer's spatula (wooden) ,	made in many countries the same type
Ayer's spatula (plastic)	''
Cyto-Brush	made in U.K.
cervi-brush	''
Endocervical sampler	''
Cotton Swab	also supplied by countries.
CytoPick	Japan
Gynoscann	Portugal
Spatulas and cotton Swabs	Germany (Paul Boettger ohg company)
Cyto-spatula for cervical smear	made in Switzerland

The device-EosSmear is the Ayer's spatula type with screw round top for easily scraping and removing the cytological material from the surface of the cervix or vagina; and the back of the design is for scraping also of the cervical area and SCJ part of the body.

The device is not a special or very new device, but a common and same type , traditional device that used for Pap. s.. As in the world the spatula is not a special one, people supply the same-premarketed devices as Ayer's spatula in wooden or plastic materials, or Cyto-brush types but with their own brand name , so as the EosSmear is the same usage, intended use, same safety and effectiveness for which is the substantial equivalence to the premarketed devices,disposable,low cost and light weight.

The cervical spatula, some doctors used with sterilized, or non-sterilized. As it touches the body surface at very short time, so we made tests of material test which shows non-heavy metal contents of our device,; and the sterility test proves the device is safe and hygiene , no harm to patients due to the sterilization by GAMMA Radiation is approved.